Submitter : Ms. Loretta Knight **Date:** 04/26/2005

Organization : Bon Secours Outpatient Mental Health Clinic

Category : Psychiatric Hospital

Issue Areas/Comments

GENERAL

GENERAL

i.e. See Attachment

CMS-1325-P-401-Attach-1.DOC

April 14, 2005

Dr. Mark McClellan
Administrator
Center for Medicare and Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Part B Competitive Acquisition Program, Categories of Drugs to be Included under CAP

Dear Dr. McClellan:

I am writing in strong support of the proposed rule recently issued by the Centers for Medicare and Medicaid Services (CMS) that addresses implementation of the Competitive Acquisition Program (CAP). This program has tremendous potential to benefit individuals with severe and persistent mental illnesses for whom injectable medications can help maintain adherence to drug regimens, treatment that is life-saving and essential to successful rehabilitation outcomes. We urge that injectable antipsychotic medications be included in the initial phase of CAP implementation.

Advantages of Injectable Psychiatric Medications

In 2003, the final report of the President's New Freedom Commission on mental health declared that recovery - helping individuals overcome the disabling aspects of mental illnesses - is the overarching goal of the U.S. mental health system. Addressing the means for attaining this goal, the report stated, " To achieve the promise of community living for everyone, new service delivery patterns and incentives must ensure that every American has easy and continuous access to the most current treatments and best support services." In implementing the CAP program, CMS has an opportunity to make a significant contribution to fulfilling the goals of the federal New Freedom Initiative by facilitating patient access to important psychiatric medications.

Patient noncompliance with psychotropic medication regimens is similar to that for patients who take medications for somatic illnesses. A review of the literature has found that most patients probably only take 33 - 94 percent of their prescribed drugs, with the median being about 50 percent for long-term therapy, while a sizeable percentage are wholly noncompliant.[1] For people with schizophrenia and severe mood disorders, noncompliance with medications often results in the relapse of acute symptoms, frequently resulting in negative

outcomes such as rehospitalization, loss of employment/housing, and suicide. These negative consequences for the patient are compounded by a parallel negative impact on the service delivery system: costs escalate as outpatient treatment is stymied, the use of emergency facilities increases, and hospital stays are more frequent and longer.

The use of injectable antipsychotics has been recognized as an important, evidence-based practice that addresses the noncompliance of issue of many with schizophrenia. In addition, a new type of psychotropic medications show tremendous promise in addressing the issue of partial compliance among people with mental illnesses. These new medications are injectable, but do not have the side effect profile of older injectable depot psychotropics that consumers found objectionable, including lingering pain after the injection, sedation, and other effects. While a number of the new injectable medications are currently in development (including an antidepressant), one antipsychotic, an injectable form of risperidone, has been employed successfully in community-based settings for about a year, and it has shown great promise in treating schizophrenia.

The Schizophrenia Patient Outcomes Research Team (PORT) treatment recommendations, considered one of the most important practice guidelines for the treatment of schizophrenia, find that the older injectables are an important therapy for schizophrenia, stating that depot injectables should be "strongly considered for persons who have difficulty complying with oral medication..." The emerging evidence for the use of risperidone long-acting injection seems to indicate that the new injectable antipsychotics may offer significant clinical advantages to the older depot injectables, in addition to addressing the issue of noncompliance. Compliance is a significant issue in the treatment of schizophrenia, with 50 - 70 percent of all patients being only partially compliant in the first two years of treatment. A survey of studies found that noncompliance was associated with a risk of relapse that is 3.7 times greater than that for compliant patients.[2]

Studies have found that use of long-acting injectable risperidone is associated with fewer and shorter hospitalizations[3] and improved functioning and quality of life.[4] Given the promise of these new injectable medications to improve outcomes for patients and reduce healthcare costs, and the recognition of the use of injectable depot medications as an evidence-based practice, we believe that CMS should make consumer access to injectable antipsychotic medications an urgent priority. As other new injectable psychotropics become available, we suggest that CMS prioritize efforts to enhance consumer access to these drugs.

Current Obstacles Faced by Providers Using Injectable Psychiatric Medications

Unfortunately, community mental health centers (CMHCs) and other multi-service community providers, which serve a large number of people with severe mental illnesses that are eligible for both Medicaid and Medicare, face serious obstacles in providing injectable medications. As safety-net providers, CMHCs are very often heavily burdened treatment settings that lack sophisticated information technology and a sufficient level of administrative staffing. For example, to provide the new injectable antipsychotic risperidone to patients, CMHCs must first purchase the medication, and then seek reimbursement from both Medicare (which makes only partial payment for mental health drugs) and Medicaid. Providers then bear the administrative burden of tracking the claims and the financial risk of receiving incomplete payment from one or both payers. This burden has become an impediment to expanding access to this medication to the full range of patients who could benefit from it. In some cases, CMHCs will only provide the medication to patients that are solely Medicaid beneficiaries. When injectable antipsychotics are included in the Medicare CAP program, this substantial impediment will be removed, as providers would have the option to obtain the medications from a drug vendor that will handle reimbursement from Medicare. Helping providers expand access to this medication will bring great benefit to our patients with schizophrenia.

From a brief review of the proposed rule, it appears that CMS may view oncology medications as the primary medication category to be included in the initial phase of CAP. CAP also has the potential to bring new psychiatric therapies into wider use and to significantly improve the quality of care for some of the most vulnerable people in our society - helping to "achieve the promise" of the New Freedom Initiative for people with psychiatric disabilities. We urge you to include coverage of antipsychotic injectable medications in the drug categories that compose the initial phase of CAP implementation.

Sincerely,

Loretta H. Knight
Office Manager
Behavioral Medicine

Submitter : **Ms. Maclyn Powell** **Date: 04/26/2005**

Organization : **Division of Medical Assistance**

Category : **State Government**

Issue Areas/Comments

1-15

Claims Processing Overview

Regarding file code CMS-1325-P:

Will this rule be available to Medicaid?

If this rule is available to Medicaid, will Medicaid states be able to utilize the Medicare-selected vendors?

Submitter : Dr. robin johnson **Date:** 04/26/2005

Organization : Advantage Behavioral Health

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Please include medications that are used in mental health and addiction treatment. This would make medications more readily available to many people. Most mental health providers outside of large systems do not keep injectables stocked. This makes it very hard for patients in some geographic areas to obtain their medications

Submitter : Dr. William Jordan **Date:** 04/26/2005

Organization : The Center for Cancer and Blood Disorders

Category : Physician

Issue Areas/Comments

1-15

Overview of the CAP

It is evident that the primary purpose of the CAP program is to save money for the Medicare program. By setting the bidding at ASP + 6 or below, CMS hopes to drive down its cost for drugs. CAP is also intended to serve as an alternative for physicians who wish to be relieved of the financial burdens associated with the drug acquisition business. The current ASP payment methodology used for drug reimbursement will necessitate the use of the CAP program for many physicians who are underwater on the majority of their drugs. The ASP model is a good concept but the method used to come up with ASP is flawed and has resulted in many physicians being unable to purchase many of their drugs at or below Medicare reimbursement. There needs to be a mechanism in place for addressing underwater drugs and therefore giving physicians a true ?choice? in whether they want to participate in CAP. CAP participation is currently a ?necessity? for some physicians and not a ?choice.?

There are still many unanswered questions regarding implementation, quality & service standards for vendors, and beneficiary education. These unanswered questions make it a huge risk for any physician to participate in CAP. Physicians are locked into the program for one year with no way out if the program fails to operate properly. There will be huge backlash from patients if this program fails. CMS needs to ensure that the vendor may not withhold drugs ordered by a physician for a patient for any reason.

Claims Processing Overview

Comment: Increased administrative cost and burden having to track each drug and patient based on a prescription number. This burden begins with the pharmacy management, then moves to the nursing department, and ends with the billing and reimbursement department having to bill using the prescription number. CMS should compensate physicians for managing this process from rigid inventory control, to added paperwork and staff, and for program integrity.

In addition to filing all claims with Medicare for the drug?s administration, physicians will now have to include a new prescription number(s) with the claim. Currently, our billing programs are not designed to accommodate this number. In order to incorporate the required prescription number, we will have to incur the cost of purchasing new software or editing their existing program. Under the CAP program, claims must be submitted within 14 days of the date of service. Our billing office will need to change billing practices in order to accommodate this requirement.

The CAP vendor, not the physician, will file the claim with Medicare and receive payment for the drug. Providers must send patient information to the approved vendor for coinsurance collection. This means physicians will lose control over the collection process and the vendor may aggressively pursue the patient for co-insurance collection. In many cases, patients may cease their treatment because they could not afford co-insurance.

Competitive Acquisitions Areas

Comment: The issue that vendors will not be required to offer more than one drug associated with a HCPCS code is of huge concern. While you may have different drugs within a single class, these drugs have different FDA approvals and indications and a patient?s response to one drug may be very different than another. Each person responds differently to a given drug. CMS is allowing a vendor to establish a formulary under CAP which is based on price and not quality. Patient access to certain drugs should not be limited based on CAP. Vendors should not be allowed to restrict access to drugs. Once a physician selects a vendor, that vendor should not be allowed to change the drugs they offer. If they are allowed this option, more physicians will be less likely to participate in this program due to added risk and uncertainty.

Doctors must select one CAP vendor to obtain all of their Part B drugs. Vendors would be required to supply a drug for each of the HCPCS J-codes identified, but in the case of multiple-source drugs, they would only be required to supply one manufacturer?s version. We may be forced to change a patient?s therapy based on drugs availability. These ?formularies? established by CAP vendors will be driven by price, not clinical effectiveness. Furthermore, if Least-Costly Alternative (LCA) is enforced, our physicians may not have access to all drugs and will be forced to change their patients? therapy and/or consider other treatment options.

CMS must allow physicians to purchase a drug and seek reimbursement under the ASP-based methodology if medical necessity requires a specific formulation to be administered to a patient and the vendor does not furnish that formulation.

Regional or state acquisition areas would most likely provide wider vendor participation. Physicians need to be able to obtain their drugs promptly from vendors. Smaller acquisition areas would assist in this. Vendors must be able to ship drugs 24-hours a day, 7 days a week. Approximately 1/3 of all regimens are changed on the day of treatment due to changes in the patient?s condition.

Categories of Drugs to be Included under the CAP

Comment:
Phase in - I believe that CMS should target a single specialty or small group before rolling CAP out in full force. While I realize the desire to target oncology for the potentially large savings along with providing a viable alternative for oncologists to acquire drugs, I urge CMS to be cautious in selecting a specialty that utilizes such a large volume of drugs. If there are problems with implementation it can have a damaging effect on patient access to care. My biggest concern is that no one (CMS, providers, vendors, beneficiaries) fully understands how this program is going to work and patients will be the ones to suffer. This is entirely new territory and there are still many unanswered questions in regard to implementation and quality. CMS needs to proceed with caution and not rush to implement this program on a broad scale without fully understanding how the process is going to work. As a provider, I see many problems with how to implement this program on our end and have concerns over the carrier?s ability to manage the complicated claims process.

Statutory Requirements Concerning Claims Processing

Comment: The enormous burden placed on physicians to participate in CAP without any compensation is unrealistic. Reimbursement for drug administration is still below the cost to provide the service and now CMS wants to add another administrative layer and cost to the process. The burdens include:
- Provider must submit a written prescription to the vendor for each patient treatment/drug (even though a provider writes an order for the entire course of treatment, there is nothing stating that the vendor must dispense it that way).
- Provider must include in their administration billing one or more prescription numbers necessary for the carrier to match the administration claim with the drug claim submitted by the vendor. This requires more data entry and cost on the billing end.
- Provider must notify the vendor when a drug is not administered. Again, another administrative layer and cost that does not currently exist.
- Maintain a separate drug inventory for EACH CAP drug.
- Required to provide information to vendor to assist in collection efforts against our patient. This is going to create a huge conflict between physician?s office and patient not to mention physicians want no part of collection agencies harassing their patients and causing added stress which only harms their health further.
These are all new administrative burdens the physician will have to take on that do not currently exist within the practice.

CMS needs to define ?emergency? as it relates to a physician having to justify the need to receive replacement drugs from their vendor to replace drugs taken from the physician?s inventory to treat a patient. The proposed rule requires that physicians justify the need to use drugs from their inventory by proving that they meet all of four criteria established by CMS. There is no room for human error built into this system. There will be instances where an office failed to order the drug out of oversight. This is not listed as an option that justifies using drugs out of the physician?s inventory. Under the buy-and-bill model physicians would just take the drug from their inventory and treat the patient. Under the CAP model, a patient?s treatment would have to be needlessly delayed because the CAP model does not allow a physician to use their own inventory in cases of oversight. A physician should be allowed to use stock

Contracting Process-Quality and Product Integrity Aspects

Comment: CMS needs to establish guidelines for measuring quality and service performance standards for vendors. CMS needs to address issues related to shipment errors, counterfeit drugs, and timely delivery of drugs.

GENERAL

GENERAL

If we were to participate in the CAP, our clinic will still incur all the costs with procurement, storage, inventory management, and disposal of drugs. With drugs received through the CAP, our pharmacy will need maintain a patient-specific inventory for each patient. We do not have the inventory system to accurately store the medication.
The regulations need significant clarification on handling unused drugs obtained through the CAP program. For example, in terms of disposing unused drugs, CMS should clarify whether the vendor is allowed to do anything with the unused drug that is permissible under state law or whether there any restrictions under the CAP or federal law that would apply.
To ensure quality and product integrity, vendors should be prohibited from opening drug containers and physicians should be permitted to return damaged or suspicious drugs.

Submitter : Mr. Samuel Shepard

Date: 04/26/2005

Organization : American Association of Clinical Urologists

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

Note: CMS did not receive an attachment to this document. This may have been due to improper submission by the commenter or it may have been a result of technical problems such as file format or system problems.

Submitter : Ms. Maclyn Powell **Date:** 04/26/2005

Organization : Division of Medical Assistance

Category : State Government

Issue Areas/Comments

1-15

Claims Processing Overview

Claims Processing Overview:

For Medicare-Medicaid beneficiaries, will Medicare-selected vendors be expected to bill Medicaid for the co-insurance and deductible after billing Medicare?

Submitter : Dr. Gregory Friess **Date:** 04/26/2005

Organization : The Center for Cancer and Blood Disorders

Category : Physician

Issue Areas/Comments

1-15

Claims Processing Overview

Increased administrative cost and burden having to track each drug and patient based on a prescription number. This burden begins with the pharmacy management, then moves to the nursing department, and ends with the billing and reimbursement department having to bill using the prescription number. CMS should compensate physicians for managing this process from rigid inventory control, to added paperwork and staff, and for program integrity.

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Contracting Process-Quality and Product Integrity Aspects

CMS needs to establish guidelines for measuring quality and service performance standards for vendors. CMS needs to address issues related to shipment errors, counterfeit drugs, and timely delivery of drugs.

Categories of Drugs to be Included under the CAP

Phase in - I believe that CMS should target a single specialty or small group before rolling CAP out in full force. While I realize the desire to target oncology for the potentially large savings along with providing a viable alternative for oncologists to acquire drugs, I urge CMS to be cautious in selecting a specialty that utilizes such a large volume of drugs. If there are problems with implementation it can have a damaging effect on patient access to care. My biggest concern is that no one (CMS, providers, vendors, beneficiaries) fully understands how this program is going to work and patients will be the ones to suffer. This is entirely new territory and there are still many unanswered questions in regard to implementation and quality. CMS needs to proceed with caution and not rush to implement this program on a broad scale without fully understanding how the process is going to work. As a provider, I see many problems with how to implement this program on our end and have concerns over the carrier?s ability to manage the complicated claims process.

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: The enormous burden placed on physicians to participate in CAP without any compensation is unrealistic. Reimbursement for drug administration is still below the cost to provide the service and now CMS wants to add another administrative layer and cost to the process. The burdens include:
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Doctors must select one CAP vendor to obtain all of their Part B drugs. Vendors would be required to supply a drug for each of the HCPCS J-codes identified, but in the case of multiple-source drugs, they would only be required to supply one manufacturer?s version. We may be forced to change a patient?s therapy based on drugs availability. These ?formularies? established by CAP vendors will be driven by price, not clinical effectiveness. Furthermore, if Least-Costly Alternative (LCA) is enforced, our physicians may not have access to all drugs and will be forced to change their patients? therapy and/or consider other treatment options.

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Overview of the CAP

It is evident that the primary purpose of the CAP program is to save money for the Medicare program. By setting the bidding at ASP + 6 or below, CMS hopes to drive down its cost for drugs. CAP is also intended to serve as an alternative for physicians who wish to be relieved of the financial burdens associated with the drug acquisition business. The current ASP payment methodology used for drug reimbursement will necessitate the use of the CAP program for many physicians who are underwater on the majority of their drugs. The ASP model is a good concept but the method used to come up with ASP is flawed and has resulted in many physicians being unable to purchase many of their drugs at or below Medicare reimbursement. There needs to be a mechanism in place for addressing underwater drugs and therefore giving physicians a true ?choice? in whether they want to participate in CAP. CAP participation is currently a ?necessity? for some physicians and not a ?choice.?

There are still many unanswered questions regarding implementation, quality & service standards for vendors, and beneficiary education. These unanswered questions make it a huge risk for any physician to participate in CAP. Physicians are locked into the program for one year with no way out if the program fails to operate properly. There will be huge backlash from patients if this program fails. CMS needs to ensure that the vendor may not withhold drugs ordered by a physician for a patient for any reason.

GENERAL

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The regulations need significant clarification on handling unused drugs obtained through the CAP program. For example, in terms of disposing unused drugs, CMS should clarify whether the vendor is allowed to do anything with the unused drug that is permissible under state law or whether there any restrictions under the CAP or federal law that would apply.
To ensure quality and product integrity, vendors should be prohibited from opening drug containers and physicians should be permitted to return damaged or suspicious drugs.

Submitter : **Mr. Michael Eging** **Date: 04/26/2005**

Organization : **Hoffmann-La Roche Inc.**

Category : **Drug Industry**

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1325-P-409-Attach-1.DOC

April 26, 20005

BY HAND DELIVERY

Dr. Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1325-P (Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals under Part B)

Dear Administrator McClellan:

Hoffmann-La Roche Inc. ("Roche"), a research-based pharmaceutical company, submits the following comments in response to the proposed rule implementing provisions of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("MMA") that require implementation of a competitive acquisition program for certain Medicare Part B drugs not paid on a cost or prospective payment system basis. [1] We appreciate the work undertaken by the Centers for Medicare and Medicaid Services ("CMS") to implement the MMA and welcome the opportunity to present our suggestions on ways to improve this proposed rule so that it best serves the interests of beneficiaries, providers, and other stakeholders of the Medicare Program.

Our comments will focus on:

- The categories of drugs to be included in the competitive acquisition program;
- Claims processing, in particular the conditions under which physicians may use the competitive acquisition program to re-supply drug inventories in their offices;
- The bidding process, including how drug weights will be calculated and how new drugs will be included in the program; and
- Exclusion of competitive acquisition program prices from manufacturers' calculations of average sales price.

All of our comments are submitted in the spirit of assisting CMS's efforts to preserve beneficiaries' access to appropriate health care items and services. Pursuant to the instructions included in the Notice of Proposed Rulemaking, each comment is set forth under a caption referencing the section of the proposed rule to which that comment relates.

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[1] 70 Fed. Reg. 10736 (March 4, 2005).

Hoffmann-La Roche Inc.

340 Kingsland Street
Nutley, New Jersey 07100-1109

Roche

Categories of Drugs to be Included in CAP

Roche agrees with CMS that the Competitive Acquisition Program, or CAP, should be phased in gradually, covering only selected drug categories and in limited geographic areas, in order to ensure that this new program does not inadvertently obstruct Medicare beneficiary access to drugs and biologicals covered under Part B. CMS has recently implemented major changes to the way that drugs are reimbursed under Part B, as required under the MMA, and the Agency is still in the process of monitoring the impact of these changes on beneficiaries and other Medicare stakeholders. CAP would make further, major changes in how physicians (and ultimately, Medicare beneficiaries) access many important drug and biological therapies covered under Part B. We support CMS's efforts to phase in this new program more gradually, to avoid potentially harmful disruptions in care.

Consistent with this view, we agree with CMS's approach to limit the application of CAP to only Part B drugs provided "incident to" a physician office visit. Physicians rarely dispense certain oral anti-cancer drugs, oral immunosuppressives, oral anti-emetics, and ESRD drugs provided to patients by dialysis facilities, which are covered under Part B by virtue of specific statutory provisions in the Social Security Act. Consequently, it makes sense for CAP to be limited only to drugs that are commonly provided directly to patients by physicians and thus are covered under Part B by virtue of the "incident to" provisions of the statute. Limiting CAP to "incident to" drugs is also consistent with the overall structure of CAP, which is voluntary for physicians.

We note that CMS also has proposed to further limit CAP to drugs typically prescribed by a particular specialty group. In particular, CMS has proposed to limit CAP only to drugs commonly prescribed by oncologists, a specialty characterized by a high volume of Part B drug use. As noted above, Roche supports CMS's approach to phase in the program gradually by limiting the application of CAP to only those drugs typically prescribed by a particular physician specialty group. Roche recommends that CMS phase in CAP more gradually by selecting a lower-volume specialty for the initial implementation.

Roche also recommends that CMS define carefully those drug categories included in CAP, so that physicians understand which drugs are affected. For example, if CMS is going to include in CAP a drug category defined as "drugs typically prescribed by oncologists," the Agency should state whether this category includes drugs that are used off-label for the treatment of cancer, or for cancer supportive therapy, consistent with existing CMS policies regarding the off-label use of cancer drugs. We ask that CMS clarify in the final rule the categories of drugs selected for inclusion in CAP, and provide a specific list of HCPCS codes that are included in those categories.

Roche also supports CMS's proposal that CAP vendors would be required to bid all HCPCS codes associated with a particular drug category. We believe this proposal is consistent with both the provisions of the Social Security Act governing Part B benefits and the intent behind CAP. The statute does not provide the Secretary with authority to force single source drugs within a category to compete against one another for inclusion in the Program. CAP was never envisioned as a mechanism for limiting beneficiary access to otherwise covered Part B drugs. Therefore, we respectfully request that CMS affirm in the final rule Congress's intent to provide Medicare beneficiaries complete access to covered Part B sole source drugs.

Roche

Claims Processing Overview

CMS specifically requested comment on whether physicians must obtain all categories of drugs that a particular CAP vendor provides from the vendor, or whether physicians should be allowed to choose the categories of drugs he or she wishes to obtain through CAP.[2] Roche agrees that physicians should be permitted to select the categories of drugs that they wish to obtain through a CAP vendor. Physicians may be interested in CAP for certain categories of drugs, but not necessarily for others, and providing physicians with this choice will make it more likely that they will participate in CAP, thereby contributing to the success of the overall program.

Under the MMA, CAP vendors are not permitted to deliver drugs and biologicals to a physician except upon receipt of a prescription or written order for such drugs and biologicals.[3] The Secretary is required to establish rules to allow physicians to obtain drugs from a CAP vendor to re-supply inventories of a drug covered under CAP, but only if:

- The drugs are required immediately;
- The physician could not have reasonably anticipated the immediate requirement for the drug;
- The CAP vendor could not deliver the drugs to the physician in a timely manner; or
- The drugs were administered in an emergency situation.[4]

Because even prompt drug delivery from a CAP vendor is likely to take at least one business day, it is possible that CAP will be more costly to the Medicare program because drug administration could now involve two visits to the physician – the first visit to examine and diagnose the patient, which prompts the physician to order the drug, and a second visit to administer the drug. Under the current system, where physicians typically have Part B physician-administered drugs on hand, the evaluation of the beneficiary and the administration of the drug can be taken care of in one visit. Thus, CAP could be more costly to the Medicare program, and more burdensome to beneficiaries, who now must make two visits to the physician to obtain treatment that previously could be obtained in one visit and make a separate, second co-payment for that additional visit.

Roche recommends that CMS create a process in the final rule to allow physicians more liberal use of drugs covered by CAP from existing inventories, to allow physicians to treat a patient with a CAP drug on the day of diagnosis, so that the patient is not required to come back for a second visit. Similarly, physicians should be permitted to use drugs from inventory if the physician is seeing the patient for the first time for a particular problem, or if upon examination of the patient the physician realizes the patient's condition has changed since the drug was ordered, necessitating a different dose of the same drug or a different drug, or if the physician discovers the patient is having an adverse reaction to the existing prescription and promptly needs to be switched to another. Imposing a rule that physicians may only use CAP to re-stock inventories in an emergency is likely

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[2] 70 Fed. Reg. at 10755.

[3] Section 1847B((b)(4)(E) of the Social Security Act (2005).

[4] Id. at Section 1847B(b)(5).

to result in additional burdens on beneficiaries and increased costs to the system, as explained above. CMS should consider adopting a more expansive definition of "emergency" or defining a set of circumstances that *de facto* could not have been reasonably anticipated by the physician, in order to create a construct that works for physicians and patients and still complies with the statutory standard.

In the proposed rule CMS notes that, if for some reason a drug ordered from a CAP vendor could not be administered on the expected date of administration and could be kept safely in the physician's inventory, the physician could generate an order for the drug at the later administration time and just indicate that the drug did not need to be shipped.[5] (Of course, the vendor could not bill Medicare until the drug had actually been administered, consistent with CAP requirements.) In other words, CMS already has anticipated and created a process to address a circumstance where a physician could use drug inventory to treat a patient, and this circumstance is arguably not an "emergency" by conventional standards. CMS should give additional consideration to the broad range of instances in which physicians would need to use existing inventory to treat a patient, and provide in the final rule for a more expansive set of circumstances or provisions to use CAP to re-stock inventory.

Cap Bidding Process – Evaluation and Selection

The proposed rule sets forth a bidding process whereby prospective CAP vendors submit composite bids for drug categories covered under CAP that are calculated by assigning a weight to each individual drug bid based on the percentage of volume that each drug represents out of the total volume for the category. CMS states that for 2006, this information will be based on claims data from 2004,[6] but the Agency does not state how this information will get to vendors, or whether it will be publicly available. Because information on the weight for a particular drug included in CAP is critical to potential vendors who will be submitting bids based on this information, as well as to drug manufacturers who will be negotiating with vendors on CAP prices, it is critical that CMS make this information publicly available. Also, because CMS will be using claims data that is nearly two years old to set the weights, the Agency should also clarify in the final rule how it will treat drugs that may be included in CAP but for which there are insufficient claims data.

The MMA provides that new drugs (drugs for which a payment and billing code has not been established) will be reimbursed using the ASP+6% payment methodology.[7] But the proposed rule is silent on the process for adding new drugs into CAP if those drugs are arguably included in a drug category that is covered by CAP. A new drug that is included in a drug category covered by CAP but is not offered by CAP vendors to physicians participating in the program could be put at a significant competitive disadvantage. Further, beneficiary access to the new product is likely to be hindered if physicians participating in CAP cannot acquire the new drug from the CAP vendor, but the physician can acquire all other drugs in the category through CAP. CMS should clarify in the final rule that new drugs that are covered by a CAP category are required to be provided by CAP

[5] 70 Fed. Reg. at 10756.

[6] 70 Fed. Reg. at 10762.

[7] Section 1847A(d)(2)(A) of the Social Security Act (2005).

vendors as promptly as possible (no later than the second quarter after introduction), and vendors are to be reimbursed by Medicare at ASP+6%, as set forth in the statute.

In the proposed rule, CMS also requests comment on whether it will adjust CAP drug prices more often than annually in cases where a new drug is introduced. Although vendor contracts are for three years, CMS already contemplates making annual price adjustments for all drugs covered by CAP. Because vendors have the option of opting out of CAP once these drug prices are established by Medicare, it seems ill-advised to reset an entire category of drug prices and thereby risk potential mid-year defection of vendors who, after the prices are re-set, evaluate the economics of the contract and opt not to participate. Absent a public health emergency, it does not make sense for CMS to reset prices in the CAP program more often than annually. Roche recommends that CMS make clear in the final rule that new drugs will be reimbursed at ASP+6% until the CAP prices are re-set on an annual basis.

Inclusion of CAP in ASP Calculations

The proposed rule is silent on whether sales to CAP vendors are to be included in a manufacturer's calculation of Average Sales Price, or ASP, for a drug included in CAP. CMS has set a ceiling of ASP+6% for the composite bid for a drug category included in CAP. For this reason, and because CAP prices must include all vendor costs, vendors will have a strong incentive to aggressively push manufacturer drug prices below ASP+6%.

To maximize the capacity of CAP to generate savings for the Medicare program, and to ensure that prices negotiated by manufacturers in CAP do not have unintended ripple effects across other markets, Roche recommends that CMS state clearly in the final rule that drug sales at discounted prices negotiated between manufacturers and CAP vendors for the CAP program be excluded from a manufacturer's calculation of ASP.

The statutory language could be interpreted to allow CMS to exclude CAP sales from calculation of ASP. The statutory provisions establishing the ASP payment methodology state very clearly that the section governing calculation of ASP "shall not apply in the case of a physician who elects" for the provisions governing CAP to apply instead of the ASP provisions for the payment of drugs and biologicals.[8] Although the MMA states that a manufacturer's average sales price for a drug means "the manufacturer's sales to all purchasers ... in the United States for such drug or biological in the calendar quarter,"[9] the statute also clearly provides that the provisions governing ASP do not apply where a physician has elected to participate in CAP.[10] In other words, where physicians have elected to participate in CAP, the ASP payment methodology clearly does not apply, and thus the drug sales under the CAP program should not be included in calculation of ASP.

Given the overall purposes of the CAP program, and that the drug prices negotiated between CAP vendors and manufacturers must include all of a CAP vendor's costs for participating

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[8] Id at Section 1847A(a)(2).

[9] Id. at Section 1847A(c)(1).

[10] Id. at Section 1847A(a)(2).

in the program *and* be below the weighted ASP+6% for the entire category, CMS should affirm or clarify that CAP sales are exempt from ASP in order to avoid frustrating the purposes of the program.

Conclusion

We appreciate this opportunity to submit comments to CMS regarding its proposed rule implementing the competitive acquisition program for certain Medicare Part B drugs. In summary, our recommendations are:

- Phase in CAP gradually -- in limited geographic areas, covering only drugs provided incident to a physician's office visit and, within that category, drugs typically dispensed by a particular physician specialty group;
- Continue to require CAP vendors to bid all HCPCS codes in a drug category covered by CAP;
- Allow physicians to opt in to CAP on drug-category-by-category basis;
- Create a less restrictive, cost efficient process for physicians to use CAP to re-stock office inventories;
- Make information about drug weights used in CAP bids publicly available, and clarify how weights will be calculated for drugs introduced after 2004;
- Require vendors to promptly add new drugs to CAP in order to ensure beneficiary access to all Part B drugs and biologics, and clarify that new drugs are to be reimbursed at ASP+6% until CAP prices are re-set on an annual basis.
- Clarify that drug sales under CAP are excluded from a manufacturer's calculation of ASP.

We hope that CMS will incorporate our suggestions into its final rulemaking and look forward to working with CMS on the issues identified in our comments.

Respectfully submitted,

Michael J. Eging
Executive Director
Public Policy and Federal Government Affairs

Submitter : Ms. Jorja Sturek

Date: 04/26/2005

Organization : Allergan Inc.

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-1325-P-410-Attach-1.PDF

ALLERGAN

2525 Dupont Drive, P.O. Box 19534, Irvine, CA 92623-9534 • (714) 246-4500

April 26, 2005

VIA Electronic Submission: http://www.cms.hhs.gov/regulations/ecomments

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: CMS-1325-P; Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B; Proposed rule. (70 Fed. Reg. 10746 [March 4, 2005])

Dear Dr. McClellan:

On behalf of Allergan Inc., the manufacturer of botulinum toxin type A (BOTOX®)[1], we appreciate the opportunity to submit comments to you on the above-captioned Proposed Rule to implement the Medicare Part B Competitive Acquisition Program (CAP) for covered outpatient drugs and biologicals. The CAP presents an opportunity to improve the efficiency of the Medicare program as a purchaser of drugs and biologicals not usually self-administered by patients and to relieve physicians of the expense and administrative burden of purchasing and billing Medicare for these drugs. We are pleased to see that the Centers for Medicare and Medicaid Services (CMS) has identified the realization of these opportunities as the Agency's two objectives in developing rules and procedures to implement the CAP. We believe the following recommendations will help advance these objectives and allow for successful implementation of the CAP:

1. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (the MMA) provides for physician election to participate in the CAP by category of drug and biological (*see* Soc. Sec. Act §§ 1847B(a)(1)(A)(iii), (a)(5)(A)(i), (a)(5)(C)). CMS should allow physicians to elect which categories of drugs/biologicals to to acquire through CAP, rather than require physicians to participate on an "all or nothing" basis. Physicians who are interested in participating in the CAP to obtain certain categories of drugs and biologicals but not others should be permitted to do so consistent with the MMA.

2. CMS should not permit the creation of formularies, therapeutic substitution or least costly alternative-like policies under the CAP. The CAP is intended to offer a different mechanism for the

[1] The current package labeling includes the following indications for BOTOX®:
BOTOX® is indicated for the treatment of cervical dystonia in adults to decrease the severity of abnormal head position and neck pain associated with cervical dystonia.
BOTOX® is indicated for the treatment of severe primary axillary hyperhidrosis that is inadequately managed with topical agents.
BOTOX® is indicated for the treatment of strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and above.
The efficacy of BOTOX® treatment in deviations over 50 prism diopters, in restrictive strabismus, in Duane's syndrome with lateral rectus weakness, and in secondary strabismus caused by prior surgical over-recession of the antagonist has not been established. BOTOX® is ineffective in chronic paralytic strabismus except when used in conjunction with surgical repair to reduce antagonist contracture.
In addition, BOTOX® Cosmetic, which has distinct labeling, packaging and NDC-coding, has been approved by the FDA for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients ≤65 years of age. BOTOX® Cosmetic is never covered by Medicare.

distribution and billing for drugs and biologicals covered and paid under Medicare Part B. The CAP is not intended to change the fundamental structure of coverage for drugs and biologicals under Part B. For categories of drugs or biologicals that are included in CAP, all sole source drugs and all biologicals that are in those categories, are FDA-approved and provided incident-to a physician's service under established Medicare program rules and policies, must be offered by CAP vendors. All biologicals should be considered sole source products as there are no therapeutically equivalent forms of these agents. If a drug is a true multi-source drug and the CAP vendor includes only one supplier's brand of such drug, then the physician must have an opportunity to select an alternative brand under the "furnish as written" authority when the physician determines that the alternative brand would be in the patient's best interest. The physician must be permitted to make the furnish as written request without incurring significant administrative burdens.

3. As discussed above, the CAP is not intended to change Medicare rules and policies with respect to coverage for drugs and biologicals under Part B. CAP vendors should not be inserting themselves in the role of the physician—i.e., to determine what is in the best interest of the patient, nor should the CAP vendor insert itself in the role of the carrier—i.e., to determine whether or not a drug or biological meets the reasonable and necessary criteria for coverage. If a drug or biological would never be covered for a particular condition under the terms of a National Coverage Determination (NCD) or Local Coverage Determination (LCD), then it would appear acceptable for the CAP vendor to deny a request to supply the drug. However, absent a clear determination of non-coverage by NCD or LCD, a CAP vendor must not be permitted to refuse to supply a drug simply because it is ordered for a use beyond labeling or because an LCD approves coverage subject to certain conditions.

4. CAP vendors generally must provide physicians with a full NDC unit of a covered drug or biological. When the NDC unit is larger than the HCPCS billing unit (e.g., the NDC unit is 100 mg and the HCPCS billing unit is 10mg), there may be excess remaining after the administration to the patient (e.g., the physician administers 90 mg [9 billing units] and 10mg [1 billing unit] remains). When this excess (remnant) must be discarded, the vendor should be permitted to bill the full NDC unit consistent with Medicare's established policies for billing for unavoidable wastage.

5 In considering what groupings of drugs and biologicals to designate as "categories" for CAP purposes, CMS should look at actual practice patterns and utilization by physician specialties. CMS should allow a single drug or biological to appear in multiple categories consistent with physician utilization patterns. For example, if a drug or biological is the third most frequently used drug by one specialty and the fifth most frequently used drug by another specialty, the drug should be made available separately under the categories grouping the drugs for both specialties. This will avoid forcing physicians to elect CAP for categories that do not fit with the way in which they practice. In addition, CMS should permit different specialties in a multi-specialty group practice to elect whether or not to participate in the CAP on a specialty-by-specialty basis. This is consistent with the way CMS considers other payment policies for multi-specialty practices (e.g., whether or not a patient is considered a new or established patient is determined on a specialty-by-specialty basis for the multispecialty group practice—not for the group practice as a whole).

6. We are concerned that the inclusion of prices paid under the CAP in the determination of average sales price (ASP), for purposes of payment under Part B outside the CAP, will limit the ability of the CAP to achieve substantial savings for the Medicare program. Congress recognized that including competitively bid Part D prices under ASP would limit the ability of Part D prescription drug plans and Medicare Advantage prescription drug plans to negotiate favorable terms. Therefore, Congress excluded Part D bid prices from the determination of ASP and from the determination of Medicaid best pricing. At

the same time, Congress intended the CAP and ASP programs to be separate. Excluding CAP pricing from ASP/Medicaid best pricing, will allow greater program savings overall in the long-term.

7. CMS should not set an arbitrary limit on the number of CAP vendors with whom it will contract for a particular category or region. If there are more than five vendors with overall bid prices that meet CMS's ASP test, whose bid prices are not substantially different and who offer quality service, CMS should allow all such eligible vendors to participate in the CAP. Especially in the early phase-in period of the CAP, physicians should have maximum choice among vendors meeting overall price and service eligibility criteria. Physicians may find that the vendors differ on a category or product basis in meeting their needs and their patients' needs.

8. Under the CAP, CMS must provide for physicians to have supplies of drugs and biologicals as needed in "real world" practice settings. Physicians should be permitted to maintain inventories of drugs and biologicals and to seek replacement under the CAP, when appropriate, to avoid situations where patients would need to reschedule or return for a visit because the drug or biological has not been received from the CAP vendor.

9. In determining eligibility of bid prices, CMS should consider updated information on ASP from the latest quarter available. In updating payments to vendors in years two and three of the multi-year contracts, CMS should refer to the latest quarter available—not to ASP data that will be over one year old by the time the pricing update is implemented.

10. Whether CMS ultimately decides initially to implement the program for all drugs or just a limited number of categories and whether CMS initially implements the program nationally, regionally or on a state-by-state basis, CMS should carefully monitor the impact on patient access, physician adoption and use of the CAP, quality of services provided by CAP vendors, transactional costs for manufacturers, distributors, physicians and CAP vendors to comply with program administrative requirements as well as overall Medicare program savings. We understand that Congress created the CAP without first authorizing a demonstration project to address these issues. Therefore, it is incumbent on CMS to make sure that these issues are studied to assure that the CAP will be successful without harming beneficiaries or being unnecessarily burdensome on physicians, suppliers, manufacturers or CAP vendors.

* * * *

Thank you for considering our comments on the CAP Proposed Rule. We believe that with careful planning and consideration of comments by interested stakeholders, CMS can adopt a CAP that will meet the objectives of improving Medicare program efficiency and reducing physicians' administrative burdens. If you have any questions about our comments, please contact me at 714-246-4634 (or by e-mail at sturek_jorja@allergan.com).

Sincerely yours,

Jorja Sturek BSA

Jorja Sturek, R.Ph., M.S.
Director of Reimbursement—BOTOX®
Allergan Inc.

Submitter : **Dr. Unamarie Clibon** **Date: 04/26/2005**

Organization : **The Center for Cancer and Blood Disorders**

Category : **Physician**

Issue Areas/Comments

1-15

Overview of the CAP

It is evident that the primary purpose of the CAP program is to save money for the Medicare program. By setting the bidding at ASP + 6 or below, CMS hopes to drive down its cost for drugs. CAP is also intended to serve as an alternative for physicians who wish to be relieved of the financial burdens associated with the drug acquisition business. The current ASP payment methodology used for drug reimbursement will necessitate the use of the CAP program for many physicians who are underwater on the majority of their drugs. The ASP model is a good concept but the method used to come up with ASP is flawed and has resulted in many physicians being unable to purchase many of their drugs at or below Medicare reimbursement. There needs to be a mechanism in place for addressing underwater drugs and therefore giving physicians a true ?choice? in whether they want to participate in CAP. CAP participation is currently a ?necessity? for some physicians and not a ?choice.?

There are still many unanswered questions regarding implementation, quality & service standards for vendors, and beneficiary education. These unanswered questions make it a huge risk for any physician to participate in CAP. Physicians are locked into the program for one year with no way out if the program fails to operate properly. There will be huge backlash from patients if this program fails. CMS needs to ensure that the vendor may not withhold drugs ordered by a physician for a patient for any reason.

Categories of Drugs to be Included under the CAP

Phase in - I believe that CMS should target a single specialty or small group before rolling CAP out in full force. While I realize the desire to target oncology for the potentially large savings along with providing a viable alternative for oncologists to acquire drugs, I urge CMS to be cautious in selecting a specialty that utilizes such a large volume of drugs. If there are problems with implementation it can have a damaging effect on patient access to care. My biggest concern is that no one (CMS, providers, vendors, beneficiaries) fully understands how this program is going to work and patients will be the ones to suffer. This is entirely new territory and there are still many unanswered questions in regard to implementation and quality. CMS needs to proceed with caution and not rush to implement this program on a broad scale without fully understanding how the process is going to work. As a provider, I see many problems with how to implement this program on our end and have concerns over the carrier?s ability to manage the complicated claims process.

Statutory Requirements Concerning Claims Processing

The enormous burden placed on physicians to participate in CAP without any compensation is unrealistic. Reimbursement for drug administration is still below the cost to provide the service and now CMS wants to add another administrative layer and cost to the process. The burdens include:
- Provider must submit a written prescription to the vendor for each patient treatment/drug (even though a provider writes an order for the entire course of treatment, there is nothing stating that the vendor must dispense it that way).
- Provider must include in their administration billing one or more prescription numbers necessary for the carrier to match the administration claim with the drug claim submitted by the vendor. This requires more data entry and cost on the billing end.
- Provider must notify the vendor when a drug is not administered. Again, another administrative layer and cost that does not currently exist.
- Maintain a separate drug inventory for EACH CAP drug.
- Required to provide information to vendor to assist in collection efforts against our patient. This is going to create a huge conflict between physician?s office and patient not to mention physicians want no part of collection agencies harassing their patients and causing added stress which only harms their health further.
These are all new administrative burdens the physician will have to take on that do not currently exist within the practice.

CMS needs to define ?emergency? as it relates to a physician having to justify the need to receive replacement drugs from their vendor to replace drugs taken from the physician?s inventory to treat a patient. The proposed rule requires that physicians justify the need to use drugs from their inventory by proving that they meet all of four criteria established by CMS. There is no room for human error built into this system. There will be instances where an office failed to order the drug out of oversight. This is not listed as an option that justifies using drugs out of the physician?s inventory. Under the buy-and-bill model physicians would just take the drug from their inventory and treat the patient. Under the CAP model, a patient?s treatment would have to be needlessly delayed because the CAP model does not allow a physician to use their own inventory in cases of oversight. A physician should be allowed to use stock.

Competitive Acquisitions Areas

The issue that vendors will not be required to offer more than one drug associated with a HCPCS code is of huge concern. While you may have different drugs within a single class, these drugs have different FDA approvals and indications and a patient?s response to one drug may be very different than another. Each person responds differently to a given drug. CMS is allowing a vendor to establish a formulary under CAP which is based on price and not quality. Patient access to certain drugs should not be limited based on CAP. Vendors should not be allowed to restrict access to drugs. Once a physician selects a vendor, that vendor should not be allowed to change the drugs they offer. If they are allowed this option, more physicians will be less likely to participate in this program due to added risk and uncertainty.

Doctors must select one CAP vendor to obtain all of their Part B drugs. Vendors would be required to supply a drug for each of the HCPCS J-codes identified, but in the case of multiple-source drugs, they would only be required to supply one manufacturer?s version. We may be forced to change a patient?s therapy based on drugs availability. These ?formularies? established by CAP vendors will be driven by price, not clinical effectiveness. Furthermore, if Least-Costly Alternative (LCA) is enforced, our physicians may not have access to all drugs and will be forced to change their patients? therapy and/or consider other treatment options.

CMS must allow physicians to purchase a drug and seek reimbursement under the ASP-based methodology if medical necessity requires a specific formulation to be administered to a patient and the vendor does not furnish that formulation.

Regional or state acquisition areas would most likely provide wider vendor participation. Physicians need to be able to obtain their drugs promptly from vendors. Smaller acquisition areas would assist in this. Vendors must be able to ship drugs 24-hours a day, 7 days a week. Approximately 1/3 of all regimens are changed on the day of treatment due to changes in the patient?s condition.

Claims Processing Overview

Increased administrative cost and burden having to track each drug and patient based on a prescription number. This burden begins with the pharmacy management, then moves to the nursing department, and ends with the billing and reimbursement department having to bill using the prescription number. CMS should compensate physicians for managing this process from rigid inventory control, to added paperwork and staff, and for program integrity.

In addition to filing all claims with Medicare for the drug?s administration, physicians will now have to include a new prescription number(s) with the claim. Currently, our billing programs are not designed to accommodate this number. In order to incorporate the required prescription number, we will have to incur the cost of purchasing new software or editing their existing program. Under the CAP program, claims must be submitted within 14 days of the date of service. Our billing office will need to change billing practices in order to accommodate this requirement.

The CAP vendor, not the physician, will file the claim with Medicare and receive payment for the drug. Providers must send patient information to the approved vendor for coinsurance collection. This means physicians will lose control over the collection process and the vendor may aggressively pursue the patient for co-insurance collection. In many cases, patients may cease their treatment because they could not afford co-insurance.

Contracting Process-Quality and Product Integrity Aspects

CMS needs to establish guidelines for measuring quality and service performance standards for vendors. CMS needs to address issues related to shipment errors, counterfeit drugs, and timely delivery of drugs.

GENERAL

GENERAL

If we were to participate in the CAP, our clinic will still incur all the costs with procurement, storage, inventory management, and disposal of drugs. With drugs received through the CAP, our pharmacy will need maintain a patient-specific inventory for each patient. We do not have the inventory system to accurately store the medication.
The regulations need significant clarification on handling unused drugs obtained through the CAP program. For example, in terms of disposing unused drugs, CMS should clarify whether the vendor is allowed to do anything with the unused drug that is permissible under state law or whether there any restrictions under the CAP or federal law that would apply.
To ensure quality and product integrity, vendors should be prohibited from opening drug containers and physicians should be permitted to return damaged or suspicious drugs.

Submitter : **Mrs. Terry Allen** **Date: 04/26/2005**

Organization : **South Texas Oncology & Hematology**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir:

I have had the privilege of serving Cancer Patients and their faimilies for the past 4 years as a Billing Manager.

As I work with 13 physicians I am continuously amazed at how different each physician practices medicine and the challenges that presents in billing. With the advent of ASP we have tried to establish standard protocols. To date, we have been unsuccessful.

I fail to understand how the CAP standardization of a formulary will be acceptable to different physicians. Physicians took an oath to do no harm, but if they are tied to a formulary that they feel/know is outdated and/or inadequate how are they suppose to treat the patient?

Additionally, from a billing perspective the requirements of submitting a claim are very burdensom and frankly will not be doable. Billing within 14 days is not unacceptable, but listing the individual RX #'s for each drug and ensuring that that # is tied to the medical record appropriately is very lengthy. It is reminescent of the NDC# issue. We simply do not have the resources to report and/or track the data with any confidence. Nor will our computer systems handle the data.

What I have not told you, is my mother recently passed away from Lung Cancer. My family is not bitter, because we had access to the best medical care in the world. WE as a family were allowed to make treatment decisions, not the government. The physician was allowed to treat my mother with the latest drugs and technology, not the government. My family was given a gift that is irreplaceable, 9 additional months with my mother. But more than that my mother was given an excellent quality of life. Se went from being in a wheelchair to camping with us. I dare to say with the government managing my mothers treatment the quality of life would have been much worse.

I respectfully request that you abandon the MVI CAP program as there is not enough accountablity tied to the Vendor and the burden on physician practices is too high.

Terry D. Allen

Submitter : **Mr. Scott Melville** **Date: 04/26/2005**

Organization : **Healthcare Distribution Management Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-413-Attach-1.DOC

HDMA
Healthcare Distribution
Management Association

Kurt Hilzinger, Chairman of the Board
John M. Gray, President and CEO

April 26, 2005

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Via Electronic Submission

Re: Medicare Program: Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B [CMS-1325-P] 69 Fed. Reg. 10746 (proposed March 4, 2005)

Dear Dr. McClellan:

The Healthcare Distribution Management Association (HDMA) submits the following comments in response to the Centers for Medicare and Medicaid Services (CMS) proposed rule, *Medicare Program: Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B* [CMS-1325-P] 69 Fed. Reg. 10746 (proposed March 4, 2004).

HDMA is the national trade association representing full-service distribution companies responsible for ensuring that billions of units of medication are safely distributed to tens of thousands of retail pharmacies, hospitals, nursing homes, clinics, and other provider sites across the United States. As government licensed entities, healthcare distributors ensure product safety and provide the vital link between manufacturers and healthcare providers by warehousing finished products, processing orders, keeping records, managing inventory, supplying information systems and software, processing recalls and returns, providing accounting services and extending credit. While providing these

extensive services, drug distributors' average net profit margins of 0.77 percent[1] remain very slim.

HDMA has several concerns regarding the proposed structure of the Medicare Part B Competitive Acquisition Program (CAP) as well as some of the outstanding issues CMS has yet to resolve. We appreciate that the agency has a statutory obligation to implement the CAP under the Medicare Prescription Drug Benefit, Improvement, and Modernization Act of 2003 (MMA) and understand the necessity to achieve Medicare program savings. However, this program could have a significant impact on future reimbursement and distribution models for Medicare Part B drugs. We urge CMS to proceed with caution, particularly given the additional handling and storage costs often associated with these products, as well as the special needs of the beneficiaries who receive them.

Background

A number of HDMA member companies focus part or all of their business on distributing the specialty drugs covered under Medicare Part B. These distributors offer the specific services required to meet the unique storage and handling requirements of the injectable and intravenous drugs used to treat oncology patients, inhalation therapy products, oral immunosuppressives, biotech and other prescription drugs commonly administered in physicians' offices and used by patients with serious, chronic conditions needing intensive and often expensive treatment.

When specialty drugs are channeled through the supply chain, the costs of handling such drugs escalate to meet their unique storage and handling needs. For example, most of the products covered under Part B often have short shelf-lives, require on-site refrigeration, freezing or exact temperature controls, and are accompanied by special inventory carrying costs, special packaging requirements or complex shipping procedures. Not only do healthcare distributors meet these critical specialty drug handling needs to protect the efficacy of the product, they also speed and streamline the drug ordering, transaction and shipping processes, thereby enabling providers to concentrate on the function they do best -- direct patient care.

It is important that, when structuring this program, CMS create a truly competitive environment where all parties are sufficiently educated about the requirements of the CAP so that they may participate on a level playing field. Prospective vendors must have sufficient information about the parameters of the program, vendor and physician responsibilities, and the technical and administrative aspects of the CAP, in order to accurately calculate bid amounts and help ensure that all beneficiaries who use these

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[1] Healthcare Distribution Management Association, 2004 HDMA Industry Profile and Healthcare Factbook, Figure 3 (2004).

products will ultimately receive the best service possible and access to the prescription drugs they need.

Categories of Drugs to be Included Under the CAP

This section of the proposed rule presents options for phasing in the CAP program. CMS suggests several possibilities, and requests comments on which, if any, of the options would be suitable for this new program. For example, CMS proposes including all drugs furnished incident to a physician's services; phasing in CAP drugs by physician specialty; beginning the program with one specialty physician group, such as oncologists; or by starting the program initially with a physician group that uses fewer Part B drugs in its practice area.

HDMA suggests that in addition to consideration of a phase-in approach based on specific drugs or specialty practice areas, CMS should consider establishing a pilot program in order to determine if the CAP model is in fact operationally feasible for selected vendors, electing physicians and their Part B drug patients, as well as Medicare carriers Such a pilot could be limited in scope either by region or by specialty group or both, and should include a thorough evaluation of the desired level of participation by physicians, the capacity of vendors to function under this new distribution model, and adequate access to CAP drugs for beneficiaries.

While CMS has conducted competitive bidding programs under some of its other benefits, those programs were sufficiently tested through the use of demonstration projects and extensive consultation with policy makers, carriers, and industry. We agree that some of the lessons learned during those pioneer programs can be used as guidance for the agency.

However, HDMA notes that many differences exist between delivery of Part B specialty drugs and products in past programs. For example, suppliers of durable medical equipment, referenced in the proposed rule, customarily delivered equipment and services directly to Medicare beneficiaries, collected copayments, and had claims submission and appeals processes in place before competitive bidding was implemented for that Medicare benefit. In contrast, healthcare distributors most often deliver specialty drugs to physicians' offices or institutional settings without a direct relationship with beneficiaries.

Moreover, the CAP structure, as proposed by CMS, will significantly alter the current healthcare distribution model as well as claims processes for these products. In order to facilitate a smooth transition to the new distribution model and the success of the CAP, CMS should attempt to conduct a pilot program whereby careful evaluation will pinpoint problems and flaws that can be corrected before full implementation.

Competitive Acquisition Areas

In this section of the proposed rule, CMS requests comments regarding competitive acquisition areas and whether they should be established on a national, regional or state level. The MMA dictates only that CMS establish competitive acquisition areas, defined under the statute as appropriate geographic region(s) established by the Secretary under the program but provides no guidance on the appropriate size of the areas.[2]

HDMA does not have a specific recommendation regarding the size of the geographic areas for the purposes of awarding vendor contracts, but we believe that the approach taken by CMS should be broad enough to allow some flexibility to ensure that an adequate number of vendors are available to serve each region. One approach would be for competitive acquisition areas to be established on a regional basis (e.g., multistate regions), in order to ensure that regional specialty pharmacy distributors would be able to participate without having to expand their services nationwide. Additionally, larger companies interested in contracting as national vendors should have the ability to serve the entire country if they have that ability. Therefore, CMS might establish several regional acquisition areas, but allow for national companies to submit bids for the entire country. This structure would enable prospective regional vendors to submit bids in those areas where they already do business, and would also preserve the interests of national companies that have the desire and capacity to serve a larger area and larger customer base.

In addition, once CMS determines the parameters of the competitive acquisition areas, the agency should provide to the prospective vendors a comprehensive description of each area so that the vendors may make a thoroughly informed decision about whether they are able to serve the area(s) and at what bid amounts. For example, for each competitive acquisition area, CMS should provide bidding vendors with, at a minimum, the number of physicians in that area who are expected to elect to participate in the CAP, as well as utilization data and the estimated number of beneficiaries who use competitively biddable products in that area. Without some estimate of how many beneficiaries will be potentially served, the bidders will be unable to accurately calculate costs related to the delivery environment, claims volume, and storage and handling needs for CAP drugs, and thus be unable to accurately determine appropriate bid amounts. By providing these parameters, CMS will help to ensure that the CAP bid process is more efficient and the resulting reimbursement rates are a true reflection of all costs involved.

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[2] Medicare Prescription Drug Benefit, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§ 1847B (1)(A)(i), (2)(C) (2003).

Claims Processing Overview

According to the proposed rule, payment for drugs furnished under the CAP is conditioned upon drug administration by the physician. While we recognize that CMS must have a reasonable assurance that a beneficiary has received the appropriate drug before approving payment, HDMA has serious concerns about the proposed process for linking claims for CAP drugs with physician claims for drug administration.

The complexity of the claims process as described by CMS in the proposed rule is troublesome because it places vendors in a position of reliance on other parties for payment for delivered drugs. First, reimbursement to healthcare distributors for CAP drugs under the program will be contingent upon submission of claims for the drugs themselves, physician-submission of claims for administration of the drugs, and matching of those claims by CMS, which may be filed with two or more different carriers.

We acknowledge that this structure has been predetermined in part by the Medicare statute, but HDMA urges CMS to exercise some discretion in establishing a more workable system. For instance, CMS should consider whether it is possible for one carrier to administer claims for all CAP products in a competitive acquisition area. If all claims – submitted by physicians and vendors -- were processed by the same carrier, as opposed to multiple carriers, there may be a greater likelihood that carrier staff would have the opportunity to become more familiar with the program, and physicians and vendors would be better able to coordinate claims issues if handled uniformly by one office. Furthermore, regardless of whether physicians and vendors submit claims to one or multiple carriers, CMS should establish a separate office or special ombudsman solely dedicated to issues that may result from this cross-claim matching concept.

Second, under the proposed rule, a vendor would have little control over the claims practices of a physician who is a participant in the CAP. Should a physician fail to file a claim in a timely manner, or file an inaccurate claim, payment will be further delayed for the vendor and the vendor may have little or no recourse. It follows that if a physician claim is subject to post-payment denial and recoupment by the carrier, vendors would also face the burden of recouped reimbursement amounts. Whereas vendors have no role in determination of medical necessity or prescribing of CAP drugs, they are subject to reliance upon the physician's expertise and ethical conduct.

CMS has proposed that physicians electing to participate in the CAP may be held to a 14 day prompt claim submission requirement and HDMA supports this concept. CMS should also institute appropriate penalties, such as exclusion from the CAP, for physicians who abuse the process or have repeated incidents of incorrect or late claims filing. In addition, HDMA encourages CMS to evaluate whether this delivery and reimbursement model is realistic considering the risks involved for healthcare distributors who participate.

Third, once a claim for administration of a CAP drug has been submitted by a physician, CMS anticipates that the claim would be adjudicated by the physician's local carrier which would check that the physician was billing for appropriate drugs from the selected drug vendor and that the claim was compliant with all local coverage determinations (LCD). It has been brought to HDMA's attention that there may be some concern regarding whether the local carrier may also apply its least costly alternative policy to the claim submitted under the CAP, despite the establishment of pre-determined CAP reimbursement rates.

LCD edits should be limited to coverage and should not apply least costly alternative policies to already agreed upon CAP rates for Part B drugs. If CAP products are subject to this practice, it will be difficult for vendors who may deliver only the specific drugs ordered by the electing physician. Vendors attempting to collect the higher co-pay for a product whose allowable is above the least costly agent will have no mechanism in place to provide the patient with an Advance Beneficiary Notice permitting the vendor to bill the patient for the more expensive product. Additionally, Medicare carriers do not uniformly apply this policy. In fact, some carriers have not implemented the policy, and still others have suspended or are considering suspending it until they determine the impact of the new ASP+6% methodology.

The expectation that vendors will be able to manage the accounting of all of the individual carriers' application of this policy in addition to their quarterly allowables, and do what is necessary to recoup their own costs means that ultimately patients' access to the most appropriate therapy could be limited. HDMA also contends that vendors entering into the CAP have agreed to supply specialty drugs at specific prices as determined by the bidding process. To impose additional limitations or reductions in reimbursement rates would be unfair to the parties who enter into CAP contracts and have an understanding of reimbursement terms as set by CMS through the application and bidding process.

HDMA is also very concerned about the collection of any deductible and coinsurance by the vendor. Under the MMA, vendor-contractors are required to collect such amounts directly from beneficiaries. In part, this will relieve physicians who opt to participate in the CAP from any responsibility they currently have regarding collection of beneficiary copayments. However, distributors typically do not have direct patient contact and potentially, will have difficulty in securing copayments from beneficiaries. CMS appears to envision this process as working much like coinsurance collection works currently under the Medicare Part B durable medical equipment (DME) benefit, but unlike DME suppliers, CAP drug vendors will not be serving patients directly.

Additionally, under the proposed rule selected vendors would not be permitted to bill beneficiaries for coinsurance amounts until after receiving final payment for the drug provided and administered by the physician. HDMA is concerned that some time may pass between the time of the beneficiary's office visit, claims submission and processing

by the carrier and the final payment to the vendor. Because this will most likely involve a time period of at least one month after the beneficiary has received the drug, it may be difficult for beneficiaries to keep track of their coinsurance amounts, and they may not be inclined to pay a vendor with whom they only have an impersonal business relationship.

HDMA suggests, as an alternative, that CMS develop a method for the physician to collect the copayment amount on behalf of the vendor at the time of the administration of the drug. Other solutions include CMS approval of an electronic payment method by which the vendor can bill the beneficiary for the coinsurance amount as soon as the drug has been administered, or granting vendors access to the common working file in order to track claims for the drugs delivered to and administered by electing physicians.

CMS has also suggested in the proposed rule that it is accepting comments regarding partial payment of claims for vendors in cases where the corresponding physician's claim has not been received within 28 days of the anticipated administration date. Partial payment would be made to the vendor upon submission of a claim for a drug it delivered to a physician and if the physician's claim is received within 90 days and matches the vendor's claim, the remainder of the payment would be paid as well. In the event that it is not matched within 90 days then the carrier could recover the claim.

HDMA supports this proposal as a minimal step. Partial payment, if applied under the CAP, would help ensure that vendor costs resulting from the special handling, storage, and transportation needs of Part B specialty products are recovered by vendors in a timely manner. CMS should consult further with individual vendors to determine an appropriate percentage for the partial payment amount.

Although HDMA supports this concept, we wish to reemphasize that it is a minimal step necessary to address the concerns noted above, such as the lack of direct patient contact and the lengthy time period between the beneficiary's office visit and the final payment to the vendor. HDMA encourages consideration of alternative measures, including full payment upon drug delivery or administration, to avoid having the substantial payment uncertainties discourage potential vendors from bidding to participate.

Contracting Process - Quality and Product Integrity Aspects

HDMA agrees that vendors should meet "quality, service, financial performance and solvency standards" including the requirement that any contractor selected should "comply with any product integrity safeguards as may be determined to be appropriate by the Secretary." These include any "...State licensing requirements and...any State or Federal requirements for wholesale distributors of drugs or biologics in States where they furnish drugs for the CAP."

HDMA would specifically like to comment on Section C.1.b. *Product Integrity* of the preamble on pages 10758 - 10760. This section discusses the ability of the vendor to ensure product integrity and indicates that the applicant should include utilization of adequate security measures to assure that processing, handling, storage, and shipment are performed in such a manner as to guard against acquiring or distributing adulterated or misbranded products. HDMA agrees that CMS should evaluate any applicant for their ability to safeguard the quality and integrity of the products they distribute.

HDMA believes that product integrity should be a high priority, if not the highest priority, consideration when determining which applicants are eligible for the CAP program. The increase in both the volume of counterfeit drug products and the sophistication of the counterfeiters is a significant concern of wholesale distributors, state and federal regulatory and legislative authorities, and the public. Considerable attention has been paid to determining how best to safeguard drug product integrity against this emerging threat.

Given these concerns, HDMA developed its "Recommended Guidelines for Pharmaceutical Distribution System Integrity" ("HDMA Guidelines" or "Guidelines") in 2003 as one means to help ensure the integrity of prescription drugs. They are intended to be used by distributors who plan to purchase prescription drug products from an alternative (non-manufacturer) source vendor. The Guidelines suggest information and methods for evaluating potential trading partners prior to establishing a business arrangement and we have supported their use for this purpose.

HDMA suggests several clarifications to the use of these Guidelines as contemplated in the preamble.

First, the Guidelines were not developed with the intention of applying them to business arrangements between a wholesale distributor and the manufacturers of the prescription drugs. Rather, they were meant to be used by a purchasing distributor when they were considering establishing a business relationship with another prescription drug distributor. Additionally, given the very heavy FDA regulation and inspection of drug product manufacturers, it is not necessary for a distributor to duplicate FDA responsibilities. Thus, we recommend that CMS clarify that they do not expect the HDMA Guidelines to be used prior to purchasing drugs directly from manufacturers.

It was also HDMA's intention to create a set of Guidelines that were flexible enough to be used in a manner that suited the circumstances of the individual firms that are considering a business arrangement. That is, the type and intensity of the scrutiny by a prescription drug purchaser evaluating a possible prescription drug seller should depend on the number of products and purchases, the type of product(s), the size of the firm, how rigorous the applicable State wholesale distribution licensure regulations are, and many other factors. For example, a distributor who is evaluating a potential new business partner is likely to give the new firm a far more rigorous review than would be needed for

a firm with which they have had a longstanding and satisfactory business relationship over a period of years.

Thus, we ask that CMS acknowledge that certain differences will exist and allow the applicants the flexibility to tailor the use of the HDMA Guidelines to the needs of the individual buying circumstances. Should CMS have any questions regarding the HDMA Guidelines, we would be happy to meet with the appropriate staff to provide further explanations, as appropriate.

Provisions of the Proposed Rule/CAP Contracting Process/Bidding Entity Qualifications

On page 10761 of the preamble, CMS states that "We would also require that the vendor **certify** that any subcontractor or subsidiary also maintains a license that complies with state regulations in every applicable State." (Emphasis added).

HDMA agrees with this requirement for the vendor's subsidiaries. However, we recommend an alternative to this requirement for subcontractors. There are several reasons for this recommendation.

First, if there are state regulations and licensure requirements, it should be the responsibility of the State granting the license to ensure that the firm they are licensing is legitimate and complies with its laws. Compliance should have been determined by appropriate state officials before the license is granted, not by another business after the fact. Otherwise, there may be questions about conflict of interest and whether a vendor could be objective in evaluating the compliance of a potential business partner.

We also wish to note that there is often no equivalent requirement for the state to cooperate by providing the information that a vendor may need to "certify" compliance. Further, states are not always required to provide information that would be helpful in assessing a subcontractor in a timely fashion, and some states have business confidentiality laws that may prevent dissemination of related information.

Additionally, one of the reasons for establishing a contractual arrangement with another entity is to be able to tap into another source of expertise, including expertise with compliance and applicable regulations. A wholesale drug distributor may choose, for example, to subcontract with a third party logistics operator to transport and deliver the prescription drugs to their customers in part because these operators have greater knowledge of the applicable transportation regulations.

HDMA recommends that CMS change the requirement so that the vendor would "certify" that they have performed appropriate due diligence necessary to verify the subcontractor's compliance status. This might include, for example, a verification of the

subcontractor's state license(s), review of recent inspection report(s), and further investigations if any questions are raised about the subcontractor's status.

In the alternative, HDMA requests that CMS clarify its expectations and intent when calling for a vendor to "certify that any subcontractor ... also maintains a license that complies with state regulations". Further clarification will allow potential bidders to more fully assess their role in providing this information so that appropriate steps can be taken when evaluating potential subcontractors, and that the appropriate information can be furnished in an application.

Cap Bidding Process – Evaluation and Selection

As mentioned throughout our comments, Part B specialty drugs require special handling, storage, and transportation methods, as well as costs associated with spillage, breakage, waste, or loss, that go above and beyond distribution conditions and costs associated with more traditional drug products. CMS should be aware of these costs and distribution needs and try to ensure that they are adequately reflected in the Medicare reimbursement rates for Part B drugs resulting from the new CAP.

HDMA has significant concerns that requiring potential vendors to submit bids below 106 percent of the manufacturers' Average Sales Price (ASP) will be problematic. The ASP-based reimbursement model has not yet been fully evaluated and it is unclear whether it is an appropriate basis for reimbursement for Part B specialty products commonly administered by physicians. Additionally, by structuring a competitive process using the ASP amount as a ceiling, HDMA is concerned that CMS may be artificially limiting vendors abilities to offer bid prices that are truly reflective of the costs involved with specialty drugs, as well as the as yet undetermined costs which may result from this new distribution model.

HDMA appreciates CMS' objectives in carrying out a competitive program and seeking ways to reduce costs to the Medicare program, but we caution the agency to be mindful of the impact such a ceiling on bid amounts could have on the ability of prospective vendors to participate, and to provide the necessary services required by the CAP drug products. In the alternative, HDMA recommends that CMS use fee schedule amounts in effect prior to implementation of the MMA as a limit on vendor current bids. This practice would help to ensure that bid submissions more adequately reflect all costs related to CAP products, while still aiming to achieve program savings. Moreover, it would give the agency sufficient time to thoroughly evaluate whether the ASP model is appropriate for Part B drug reimbursement and whether it is an accurate reflection of the current market.

Vendor or Physician Education

In its proposed rule, CMS implies that Medicare carriers will be responsible for vendor and physician education regarding the CAP and changes that will result in current practices for the parties involved. HDMA recommends that CMS continue to stay actively involved in this process, rather than leaving all supplier and provider education up to the carriers. Additionally, we urge CMS to stay in close contact with the CAP carriers and encourage uniformity in policy matters in order to prevent further confusion for doctors and vendors participating in this new program.

As an integral part of this education effort, HDMA suggests that CMS, in conjunction with the carriers responsible for the program, conduct a bidders' conference for potential vendors. This should be an open forum at which potential vendors can receive all information that they will need to submit bids and become aware of their responsibilities should they be selected. Included in this session should be information on details related to the claims process, collection of copayments, relationships with electing physicians, the appeals process, appropriate contacts at the carriers and at CMS, as well as other details about what they can reasonably expect if chosen as a vendor. Much of the CAP is dependent on a new distribution model, and it is imperative for its success, and to ensure that beneficiaries continue to receive the Part B drugs they need, to provide adequate education for suppliers as well as an available point of contact for when problems and questions arise.

Beneficiary Education

Many of the beneficiaries may already be receiving treatment by physicians which include the administration of Part B drugs included in the CAP. Transition to a new program will be smoother for beneficiaries and providers alike as long as adequate education and timely notice of changes is provided to both current and new beneficiaries.

Beneficiaries currently receive these prescription drug products in their physician's office. While this practice is not going to change under the CAP, patients will no longer be expected to pay a coinsurance amount to the physician for the drugs they receive. Instead, the physician will submit a claim to the program for a fee for administering the drug to the patient. The patient will receive a bill for a copayment amount from the vendor, perhaps as much as a month's time (or longer) since the treatment. The vendor will not have had a previous billing relationship with the beneficiary and the beneficiary will not be used to having to submit a copayment later on. Beneficiaries need to receive information about the details of the program from CMS so that they can better understand the differences for them under the CAP and their new responsibilities to both the physician and the vendor.

HDMA recommends that to ensure a smooth transition, CMS should conduct an education and awareness campaign in order to ensure that beneficiaries are well-informed about the new program including the addition of a new vendor to their healthcare team. Such a program could include open forums for physicians in order to help foster their patients through the new system, brochures or other media, such as easy-to-understand program instructions on the Medicare Web site or development of a special hotline dedicated to CAP beneficiaries.

Conclusion

HDMA appreciates the opportunity to provide you with the above comments regarding the Medicare Competitive Acquisition Program for Part B drugs. We are available for further discussion should you have questions or need additional information. Please do not hesitate to contact me or Elizabeth Gallenagh, Associate Director, Regulatory Affairs at 703-885-0234.

Sincerely,

Scott Melville

Scott Melville
Senior Vice President
Government Affairs

Submitter :

Date: 04/26/2005

Organization :

Category : Individual

Issue Areas/Comments

1-15

Overview of the CAP

CMS is rushing to implement a new system that will dramatically change how a physician cancer clinic operates. The goal of cost savings will not be reached as the individual practices will struggle to change their current ways of practice in such a rapid manner, thereby giving rise to inefficiences and potential harm to the patients. CMS should continue to investigate the inner workings of a physician cancer clinic to fully understand the impact of CAP, or any other major shift in patient treatment BEFORE making such change effective.

Contracting Process-Quality and Product Integrity Aspects

Vendor quality control is of huge concern. Practices will be locked in to one vendor for the year. If they experience quality issues, shipment delays, incorrect shipments, etc there will be no recourse. Additionally, the oncology drugs require much care in handling, many must be kept at specific temperatures during transport and holding. Physician practices are already equipped to handle these drugs and knowledgeable in this area. If spoliage occurs and is not detected by the physician, patient care will be severely compromised.

Categories of Drugs to be Included under the CAP

It is my understanding that the vendors will in effect be able to create formularies that the physicians will have to adhere to. The treatment of cancer is highly complex and subject to the advanced knowledge that oncologists have obtained and continue to obtain on a daily basis, with the issuance and new drugs and therapies. To take this out of the physicians hands completely undermines what thier role is in saving the patient's lives. If they choose to treat a certain way based on thier expert knowledge but are forced to use a different drug based on the vendor's margin analysis, the patient is who loses in the end. This is very sad and extremely scary.

Statutory Requirements Concerning Claims Processing

Operationally, CAP will cost the practice more money due to the amount of paperwork and tracking that it will require. How does this reach the ulimate goal of cost savings to the provider? It is my understanding that physician orders can be split by the vendor so the physician may not receive what they are expecting when the patient is already scheduled to be in the chair. This will be extremely inconveninent for the patient, not to mention the additional cost it will bring to the practice for rescheduling the visit.

Physicians will still incur the same costs to handle the drugs and inventory them, and there is no mechanism to reimburse the physicians for such costs.

Submitter : Joe Zuraw **Date:** 04/26/2005

Organization : Talecris Biotherapeutics

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Note: CMS did not receive an attachment to this document. This may have been due to improper submission by the commenter or it may have been a result of technical problems such as file format or system problems.

Submitter : Dr. Lance Mandell **Date:** 04/26/2005

Organization : The Center for Cancer and Blood Disorders

Category : Physician

Issue Areas/Comments

1-15

Overview of the CAP

It is evident that the primary purpose of the CAP program is to save money for the Medicare program. By setting the bidding at ASP + 6 or below, CMS hopes to drive down its cost for drugs. CAP is also intended to serve as an alternative for physicians who wish to be relieved of the financial burdens associated with the drug acquisition business. The current ASP payment methodology used for drug reimbursement will necessitate the use of the CAP program for many physicians who are underwater on the majority of their drugs. The ASP model is a good concept but the method used to come up with ASP is flawed and has resulted in many physicians being unable to purchase many of their drugs at or below Medicare reimbursement. There needs to be a mechanism in place for addressing underwater drugs and therefore giving physicians a true ?choice? in whether they want to participate in CAP. CAP participation is currently a ?necessity? for some physicians and not a ?choice.?

There are still many unanswered questions regarding implementation, quality & service standards for vendors, and beneficiary education. These unanswered questions make it a huge risk for any physician to participate in CAP. Physicians are locked into the program for one year with no way out if the program fails to operate properly. There will be huge backlash from patients if this program fails. CMS needs to ensure that the vendor may not withhold drugs ordered by a physician for a patient for any reason.

Categories of Drugs to be Included under the CAP

Phase in - I believe that CMS should target a single specialty or small group before rolling CAP out in full force. While I realize the desire to target oncology for the potentially large savings along with providing a viable alternative for oncologists to acquire drugs, I urge CMS to be cautious in selecting a specialty that utilizes such a large volume of drugs. If there are problems with implementation it can have a damaging effect on patient access to care. My biggest concern is that no one (CMS, providers, vendors, beneficiaries) fully understands how this program is going to work and patients will be the ones to suffer. This is entirely new territory and there are still many unanswered questions in regard to implementation and quality. CMS needs to proceed with caution and not rush to implement this program on a broad scale without fully understanding how the process is going to work. As a provider, I see many problems with how to implement this program on our end and have concerns over the carrier?s ability to manage the complicated claims process.

Competitive Acquisitions Areas

The issue that vendors will not be required to offer more than one drug associated with a HCPCS code is of huge concern. While you may have different drugs within a single class, these drugs have different FDA approvals and indications and a patient?s response to one drug may be very different than another. Each person responds differently to a given drug. CMS is allowing a vendor to establish a formulary under CAP which is based on price and not quality. Patient access to certain drugs should not be limited based on CAP. Vendors should not be allowed to restrict access to drugs. Once a physician selects a vendor, that vendor should not be allowed to change the drugs they offer. If they are allowed this option, more physicians will be less likely to participate in this program due to added risk and uncertainty.

Doctors must select one CAP vendor to obtain all of their Part B drugs. Vendors would be required to supply a drug for each of the HCPCS J-codes identified, but in the case of multiple-source drugs, they would only be required to supply one manufacturer?s version. We may be forced to change a patient?s therapy based on drugs availability. These ?formularies? established by CAP vendors will be driven by price, not clinical effectiveness. Furthermore, if Least-Costly Alternative (LCA) is enforced, our physicians may not have access to all drugs and will be forced to change their patients? therapy and/or consider other treatment options.

CMS must allow physicians to purchase a drug and seek reimbursement under the ASP-based methodology if medical necessity requires a specific formulation to be administered to a patient and the vendor does not furnish that formulation.

Regional or state acquisition areas would most likely provide wider vendor participation. Physicians need to be able to obtain their drugs promptly from vendors. Smaller acquisition areas would assist in this. Vendors must be able to ship drugs 24-hours a day, 7 days a week. Approximately 1/3 of all regimens are changed on the day of treatment due to changes in the patient?s condition.

Statutory Requirements Concerning Claims Processing

The enormous burden placed on physicians to participate in CAP without any compensation is unrealistic. Reimbursement for drug administration is still below the cost to provide the service and now CMS wants to add another administrative layer and cost to the process. The burdens include:
- Provider must submit a written prescription to the vendor for each patient treatment/drug (even though a provider writes an order for the entire course of treatment, there is nothing stating that the vendor must dispense it that way).
- Provider must include in their administration billing one or more prescription numbers necessary for the carrier to match the administration claim with the drug claim submitted by the vendor. This requires more data entry and cost on the billing end.
- Provider must notify the vendor when a drug is not administered. Again, another administrative layer and cost that does not currently exist.
- Maintain a separate drug inventory for EACH CAP drug.
- Required to provide information to vendor to assist in collection efforts against our patient. This is going to create a huge conflict between physician?s office and patient not to mention physicians want no part of collection agencies harassing their patients and causing added stress which only harms their health further.
These are all new administrative burdens the physician will have to take on that do not currently exist within the practice.

CMS needs to define ?emergency? as it relates to a physician having to justify the need to receive replacement drugs from their vendor to replace drugs taken from the physician?s inventory to treat a patient. The proposed rule requires that physicians justify the need to use drugs from their inventory by proving that they meet all of four criteria established by CMS. There is no room for human error built into this system. There will be instances where an office failed to order the drug out

of oversight. This is not listed as an option that justifies using drugs out of the physician?s inventory. Under the buy-and-bill model physicians would just take the drug from their inventory and treat the patient. Under the CAP model, a patient?s treatment would have to be needlessly delayed because the CAP model does not allow a physician to use their own inventory in cases of oversight. A physician should be allowed to use stock.

Claims Processing Overview

Increased administrative cost and burden having to track each drug and patient based on a prescription number. This burden begins with the pharmacy management, then moves to the nursing department, and ends with the billing and reimbursement department having to bill using the prescription number. CMS should compensate physicians for managing this process from rigid inventory control, to added paperwork and staff, and for program integrity.

In addition to filing all claims with Medicare for the drug?s administration, physicians will now have to include a new prescription number(s) with the claim. Currently, our billing programs are not designed to accommodate this number. In order to incorporate the required prescription number, we will have to incur the cost of purchasing new software or editing their existing program. Under the CAP program, claims must be submitted within 14 days of the date of service. Our billing office will need to change billing practices in order to accommodate this requirement.

The CAP vendor, not the physician, will file the claim with Medicare and receive payment for the drug. Providers must send patient information to the approved vendor for coinsurance collection. This means physicians will lose control over the collection process and the vendor may aggressively pursue the patient for co-insurance collection. In many cases, patients may cease their treatment because they could not afford co-insurance.

Contracting Process-Quality and Product Integrity Aspects

CMS needs to establish guidelines for measuring quality and service performance standards for vendors. CMS needs to address issues related to shipment errors, counterfeit drugs, and timely delivery of drugs.

GENERAL

GENERAL

If we were to participate in the CAP, our clinic will still incur all the costs with procurement, storage, inventory management, and disposal of drugs. With drugs received through the CAP, our pharmacy will need maintain a patient-specific inventory for each patient. We do not have the inventory system to accurately store the medication.
The regulations need significant clarification on handling unused drugs obtained through the CAP program. For example, in terms of disposing unused drugs, CMS should clarify whether the vendor is allowed to do anything with the unused drug that is permissible under state law or whether there any restrictions under the CAP or federal law that would apply.
To ensure quality and product integrity, vendors should be prohibited from opening drug containers and physicians should be permitted to return damaged or suspicious drugs.

Submitter : **Michael Cohen** **Date: 04/26/2005**

Organization : **National Alliance for the Mentally Ill NH**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

On behalf of the families and consumers of the National Alliance for the Mentally Ill NH, I am writing to comment on the proposed rules concerning Medicare competitive acquisition program (CAP)for Part B drugs. NAMI NH is a grassroots, membership organization that provides advocacy, education and support to New Hampshire families and consumers dealing with mental illness.

We recommend that psychiatric drugs in the CAP program be included from the beginning of this initiative. The present system is inherent with certain barriers to access for psychiatric meds that the CAP program would eliminate. We urge you to create a category that would include psychiatric medications, including long-acting or injectible anti-psychotic medications to be used for the treatment of diagnosis included in the DSM IV R. We recommend crafting a reimbursement process that adequately addresses the handling of copays and other payment issues that support the continuity of care.

Thank you for your consideration.

Sincerely,
Michael J. Cohen, MA, CAGS
Executive Director
NAMI NH
15 Green Street
Concord, NH 03301
603/225-5359

Submitter : **Ms. Ann Berkey** **Date: 04/26/2005**

Organization : **McKesson Corporation**

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

Attached please find McKesson Corporation's Comments on CMS-1325-P

CMS-1325-P-418-Attach-1.DOC

McKesson Corporation
One Post Street
San Francisco, CA 94104

Ann Richardson Berkey
Vice President
Public Affairs

[redacted]

McKESSON

April 26, 2005

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1325-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Via Electronic Submission

Re: Medicare Program: Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B [CMS-1325-P] 60 Fed.Reg. 10746

Dear Dr. McClellan:

On behalf of McKesson Corporation (hereinafter "McKesson"), we are pleased to provide our comments in response to the CMS proposed rule to implement a Competitive Acquisition Program (CAP) for certain Medicare Part B medications under Title III of the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

For over 170 years, McKesson has led the industry in the delivery of medicines and health care products to drug stores. Today, a Fortune 15 corporation, we deliver vital medicines, medical supplies, and health information technology solutions that touch the lives of more than 100 million patients each day in health care settings that include over 5,000 hospitals, 150,000 physician practices, 10,000 extended care facilities, 700 home care agencies, and 25,000 retail pharmacies. McKesson also supplies pharmaceuticals to the entire Veterans Affairs system, as well as to a significant number of Department of Defense and other government facilities. In addition, we repackage over 1.5 billion doses of drugs annually and provide analytical testing services in support of these operations.

As the largest pharmaceutical supply management and health information technology company in the world, we also have more than a decade of experience providing specialty pharmaceutical services for providers and patients with chronic conditions, including more than 60 million members of managed care plans. These high-cost, often injectable bio-pharmaceutical drugs require special handling and storage, as well as complex shipping and distribution processes to ensure product integrity. The services

associated with such complex distribution processes expand access to necessary medication treatments, increase cost-effectiveness, and improve the convenience and quality of patient care by enabling the administration of these drugs in a lower cost, outpatient setting.

McKesson has established a strong record of support and involvement in important federal and state health initiatives. We have been a pioneer in the introduction of drug savings cards to help lower the costs of pharmaceuticals through our administration of the successful Together Rx ™ card and our subsequent introduction of the CMS-endorsed Rx Savings Access™ card. The Together Rx™ card has delivered over $600 million in savings since June 2002 to more than 1.5 million low-income seniors. McKesson's Rx Savings Access™ card is providing Medicare beneficiaries with an average savings of 15-25% on the most commonly prescribed medicines and is accepted by over 95% of pharmacies nationwide. To date, more than 235,000 Medicare-eligible seniors are enrolled in this card and have realized over $52 million in savings on their prescription drugs.

McKesson has also taken a proactive approach to providing disease management programs for commercial, Medicaid and Medicare populations where we leverage our experience with patient services, pharmacy management and healthcare quality improvement activities. In nine states where we provide disease management services to Medicaid patients, we estimate those states are saving approximately two dollars for every dollar spent with McKesson, while improving both the health status of the patient population and physician satisfaction with the program. Late last year, we were awarded one of the Chronic Care Improvement Program (CCIP) demonstration projects by CMS for Medicare beneficiaries.

On the basis of our experience as both a specialty pharmaceutical distributor and a specialty pharmacy, we are pleased to comment on the proposed regulations. McKesson supports the Administration's efforts to implement a Competitive Acquisition Program; however, as one of the four companies that expressed interest in launching a national CAP, we have significant concerns about the economic feasibility of this program as it is currently proposed. We appreciate the opportunity to outline those concerns and to recommend alternative solutions.

While we elaborate further in the following pages, we wish to emphasize four key areas that are critical to the financial viability of the CAP, and thus to achieving the overall objectives of the program.

- **Ability to secure competitive acquisition costs:** CAP vendors cannot sell products for less than their acquisition price. According to our analysis of the most recent net acquisition costs and published ASPs, *many* Part B drugs *cannot be acquired* directly from the manufacturer for less than ASP+6%. To assure the financial viability of the program, CMS should allow competitive bids to be

greater than ASP+6% or create mechanisms for CAP vendors to negotiate with the manufacturers more effectively (e.g., exclude CAP pricing from ASP calculations).

- **Significant percentage of uncollectible co-payments:** Due to the shift of patient co-payment collection from the physician's office to the CAP vendor, we anticipate significant levels of uncollectible co-payments. CAP vendors must be able to collect all patient co-payments in order to justify participation in a narrow margin ASP environment.

- **Physician compliance:** Drug claim reimbursement is contingent upon several factors beyond a CAP vendor's control, including the submission and approval of physician administration claims. Physicians must have sufficient vested interest in complying with the claims submission and approval process to ensure appropriate CAP vendor payment.

- **Lost inventory:** Since CAP vendors will bear the full financial risk associated with lost, spoiled, or wasted product at the physician's office, physicians will no longer have an economic incentive to protect that inventory. CAP vendors should be able to recover legitimately documented inventory variances or wastage.

COMMENTS ON PROVISIONS OF THE PROPOSED RULE

A. Policy for the CAP

1. General Overview of the CAP

While noting the statutory requirements for an appropriate "phase in" of the program, we would strongly encourage CMS to consider launching a pilot program prior to full implementation of the CAP program. A pilot program would provide the Agency with the opportunity to identify and correct early in the process any unforeseen technical challenges that could negatively impact patients, providers, CAP vendors and the overall success of the Administration's national program. This program represents major changes to the reimbursement and distributive processes, and basic risk mitigation would suggest a pilot is required.

2. Categories of Drugs to be Included Under the CAP

We agree that the initial scope of the CAP should be limited to drugs administered as incident to a physician's service, and that a phased implementation for a select drug category is preferable. We recommend that the initial roll-out of the CAP focus on categories of oncology drugs, due to the volume and scope of Part B oncology medications. This category offers sufficient scale to promote vendor participation and to

generate significant savings to the Medicare program than if a smaller drug category, such as urology or rheumatology, is selected.

3. Competitive Acquisition Areas

Following a pilot test of a CAP, McKesson recommends national implementation of the program to provide potential CAP vendors with the ability to negotiate the best pricing. To allow regional vendor participation, we would endorse the establishment of no more than eight multi-state regional competitive acquisition areas.

B. Operational Aspects of the CAP

1. Statutory Requirements Concerning Claims Processing

The statute requires the participating physician to submit a written order or prescription before a CAP vendor is authorized to provide a covered Part B drug. We note with great interest the Agency's proposed interpretation of the terms "prescription" and "order" as interchangeable. This interpretation infers that a non-pharmacy based CAP distribution model will be utilized, which is a significant distinction since laws and regulations governing the practice of pharmacy and dispensing of prescriptions will therefore not be applicable to CAP transactions. We recommend that CMS further clarify that interpretation in the final regulations.

2. Proposed Claims Processing Overview

Physician Compliance
Under the proposed program, the CAP vendor cannot initiate reimbursement from CMS until the physician submits the administration claim. Therefore, CAP vendor reliance on the physician's clean and timely submission of drug administration claims is one of the key risks associated with the proposed program. Under the proposed regulations, a CAP vendor would bear full financial risk for all administered products even if the claims were not filed by the physician or subsequently denied by CMS. It is difficult to estimate the expected losses from non-submitted claims for several reasons:

1) this program is new and therefore there is little data on which to base this estimate; and
2) the existing data may not be representative of the volume of non-submitted claims which we anticipate.

Under the proposed claims processing system, CAP vendors will bear disproportionate financial risk relative to physicians in association with non-submitted and non-matched drug administration claims. Many physicians want to provide charitable care to patients who can not afford the drug co-payments and could do so by choosing to forego submission of the drug administration claim. However, non-submission of a claim will

deprive the CAP vendor from receiving patient co-payments and reimbursement for the product. As vendor payment is contingent on the physician's submission of claims, appropriate financial penalties and other contractual safeguards must be implemented so that physicians have an investment in assuring the submission of CAP claims.

Just as importantly, a CAP vendor will be unable to collect reimbursement if a physician's administration claim is submitted, but denied by the local carrier or by CMS. A CAP vendor cannot be expected to verify the medical necessity of a patient order prior to shipping product, particularly for off-label usage. We strongly recommend that CAP vendors should be indemnified from drug reimbursement loss associated with claim denials.

To address these concerns, we urge CMS to consider one or more of the following options:

1) include in the CAP election agreement appropriate financial penalties for physicians who fail to comply with program requirements, including the timely submission of claims and appeals, submission of patient billing data, and appropriate inventory management and controls;
2) allow CAP vendors to bill physicians for the value of the pharmaceutical product administered in association with denied or non-submitted claims;
3) require physicians to certify a patient's Part B eligibility and obtain pre-authorization from the local carrier for drug coverage;
4) designate CMS as the "payer of last resort." Under this option, CMS would fully reimburse the CAP vendor for the drug claim and bill the physician directly for costs associated with denied drug administration claims due to medical necessity or other clinical judgments;
5) grant vendors access to Medicare's common working file in order to track claims for the drugs delivered to, and administered by, electing physicians.

Furthermore, we believe it is critical that CAP vendors have the ability to terminate their relationship with a physician with two weeks notice to prevent unsustainable losses associated with serving a non-compliant physician.

Accounts Receivable

McKesson has over 30 years of experience billing and collecting Medicare claims as well as claims from all other major payers. Based upon our experience, we anticipate that, with co-payments of 20%, patient accounts receivable for CAP vendors will be significant. Under the prior AWP-based drug reimbursement methodology, physicians have routinely waived drug co-payments. In the CAP program, vendors will lose money if they are unable to collect patient co-payments. Current estimates of physician losses from uncollected co-payments range from 2% to 4% of total sales. It is difficult to estimate accurately the expected losses under the CAP for the following reasons:

- our experience indicates that collection of co-payments is significantly reduced once the patient leaves the physician office;
- uncollectible risk for CAP vendors may rise as doctors lose the economic risk associated with servicing patients who are unlikely or unable to pay; and
- CAP vendors will ship pharmaceutical products to patients who may not survive their treatment. Collection from estates will be difficult, if not impossible.

We are also concerned about the financial risk that would be assumed by CAP vendors when they continue to provide pharmaceutical products for those patients who have demonstrated an inability, or unwillingness, to pay. CAP vendors concerned about liability issues associated with discontinuing care to non-paying patients could sustain unacceptable losses. For example, patient uncollectibles of 4% would consume two-thirds of the maximum allowable gross margin of 6%, which leaves only 2% to cover direct operating costs. This does not support a viable business.

To ensure that CAP vendors are not faced with the financial necessity of having to deny medicines to non-paying patients, we strongly recommend that CMS consider the following alternatives:

1) Facilitate the development of manufacturer-sponsored patient assistance programs to allow product and patient-specific cost share assistance for qualified patients, rather than limiting patient support to foundations, endowments and similar charities. Although product-specific co-payment assistance is currently disallowed as a potential inducement under anti-kickback regulations, McKesson's market-leading position and 13 years of experience in the administration of pharmaceutical patient assistance programs can affirm that these programs can be appropriately designed and managed to assist only those patients who meet appropriate eligibility requirements.
2) Designate CMS as the "payer of last resort." Currently, drug reimbursement margins give physicians the financial flexibility to waive uncollected co-payments. After 30 days of failed attempts to collect the co-payment in the CAP program, the CAP vendor should be able to bill CMS directly for the uncollected payment.
3) Establish a quarterly allowance for uncollected payments and a reconciliation method that would permit reimbursement to CAP vendors at the average CAP vendor rate of uncollectibles.
4) Implement risk corridors around established thresholds for patient uncollectible amounts.
5) Require the physician to collect the co-payment on behalf of the CAP vendor. The CAP vendor would then collect the co-payment from the physician monthly.

Billing and Shipping Amounts
It is important that CMS confirm in the final regulations that billed and reimbursed drug claims will correspond to whole units shipped (as defined at the manufacturer's 11 digit National Drug Code) in accordance with the physician's order. While many reconstituted products are not prescribed in whole package dosages, CAP vendor reimbursement must reflect the actual quantity shipped, as required to meet the physician's order in association with an assigned Order Number. In circumstances where the use of a multi-dose vial is appropriate, we recommend that CMS reimburse in full upon receipt of the drug claim for the multi-dose product shipped. Future physician orders would be credited against this 'pre-shipment.'

Partial Payments
McKesson recommends that CMS consider an alternative claims processing approach that will fully reimburse CAP vendors for each drug claim on the expected date of administration. The Agency can then use the claims matching process as a retrospective verification of product administration only. If that is not feasible, we urge CMS to reimburse the CAP vendor at 80% of the drug claim. Without a partial payment of that magnitude, working capital costs will result in higher CAP bid prices or will deter potential vendors from bidding to participate in the CAP program.

Emergency Replacement
McKesson supports the proposed regulations for emergency replacement of product.

CAP Vendor Category Selection
To facilitate improved price negotiation with manufacturers, ease of implementation, and reduced administrative burden, McKesson recommends that the CAP election agreement specify that physicians must obtain all categories of available drugs from their contracted CAP vendor. CAP vendors will be able to utilize these economies of scale to reduce administrative costs. A physician should not be allowed to selectively obtain different drug categories from different CAP vendors.

Claims Filing
McKesson supports the proposed requirement that physicians file drug administration claims within 14 days of administration. The list of extenuating circumstances for any extensions to this 14-day period should be very narrow. If partial payments are not implemented broadly, they should be made, at a minimum, for claims that are delayed beyond the 14-day submission requirement.

Physician-provided Information
In addition to providing all of the information required under the proposed regulations, physicians should also provide the beneficiary's contact information (e.g., phone number, billing address) and credit card information. This data is necessary to enable CAP vendors to contact the beneficiaries for co-payment collection.

Inventory Management

CAP vendors must have adequate risk protection against product that is lost, spoiled or wasted in the physician's office. Even if cost estimates are included in a bid, it will be difficult for CAP vendors to accurately predict the expected risk associated with lost inventory for the following reasons:

- current loss estimates reflect a marketplace where physicians have a direct financial incentive to manage and protect inventory. As custodians of the CAP vendor's inventory, they will not have this incentive;
- physicians will continue to maintain product inventory for administration to non-Medicare patients. Without physical product segregation, it is possible that any spoiled, expired or otherwise unusable product in a physician's inventory will be attributed to CAP inventory and returned to the CAP vendor, thereby increasing inventory loss estimates;
- the proposed model creates the opportunity for inadvertent diversion into in-office inventory.

We recommend the following alternative solutions in order of preference:

1) establish risk corridors above a pre-determined expected threshold of 0.5% for inventory losses; or
2) authorize vendors to bill participating CAP physicians for shrinkage after a 0.5% loss threshold is exceeded (Note: calculated as a percentage of net sales, 0.5% is an estimate of the loss typically experienced in a well-run physician office); or
3) allow CAP vendors to discontinue shipments at their discretion to these physicians.

Fraud and Abuse

McKesson is concerned about the potential for disproportionately high use of 'furnish as written' prescriptions for products that are profitable under the current buy-and-bill model. If physicians are able to selectively utilize the CAP vendor for specific and potentially unprofitable drugs within a product category, the financial viability of the program will be threatened. As proposed, CMS "anticipates that the physician's carrier would, at times, conduct a post payment review of the use of the 'furnish as written' modifier." We support this practice and encourage CMS to *require* local carriers to conduct a claims submission review program at both the individual physician and group practice levels. Alternatively, we recommend that CAP vendors have access to 'furnish as written' claims for their customers. A CAP vendor could then submit a complaint to the local carrier requesting further investigation in cases where an audit would be appropriate.

3. Dispute Resolution

We agree with CMS that the traditional Part B appeals process is not appropriate for vendor disputes over non-payment of a drug claim. However, we are concerned that the proposed alternative dispute resolution process will be slow and cumbersome, and does not provide sufficient protection for losses associated with denied drug claims. Given the average cost of specialized therapies, the denial of a single drug claim will significantly impact already compressed vendor margins. Therefore, we strongly recommend that appropriate safeguards must be established and included in the CAP election agreement. Physicians should also be required to resubmit a clean claim and pursue an administrative appeal within seven days of notification by the designated carrier of the CAP vendor's drug claim denial. Although we recognize that some losses are inevitable, we recommend that an appropriate loss threshold be established at the contracting physician/physician group level, rather than on a per claim basis as outlined in the proposed regulations. When losses exceed $3,000 or three denied claims per UPIN number, the physician should fully reimburse the CAP vendor for the amount of the denied drug claim.

C. CAP Contracting Process

1. Quality and Product Integrity Aspects

McKesson supports requirements to ensure that vendors meet specific thresholds for financial stability. We recommend a minimum net worth or capitalization requirement of no less than $100 million. Appropriate metrics to effectively assess a vendor's financial stability would include the following:

- reviewing a contractor's net debt to capital ratio to ensure it does not exceed the 50% level. This is a key metric of financial stability and ensures the contractor can support the working capital requirements of the Medicare business. High debt levels may impede a contractor's cash flow and the ability to provide consistent inventory and service levels.
- requiring a contractor's anticipated Medicare sales to be less than 50% of their total sales. This ensures pre-existing scale and expertise in the market and limits a vendor's dependence on a profitable Medicare business to ensure his/her financial viability.

As stated in comments submitted by the Healthcare Distribution Management Association (HDMA), we believe that consideration of product integrity should be the highest priority when determining eligibility of CAP vendors. The increase in both the volume of counterfeit drug products and the sophistication of counterfeiters is a significant concern to wholesale distributors, such as McKesson, as well as to state and federal regulatory and legislative authorities, and the public. To this end, we absolutely concur that CMS must carefully evaluate vendor applicants for their ability to safeguard

the quality and integrity of the products they distribute. Additionally, each CAP vendor must comply with the Prescription Drug Marketing Act (PDMA) as well as with all applicable state and federal requirements for distributors of pharmaceuticals and biologic products.

2. Bidding Entity Qualifications

Experience and Capabilities
To ensure the credibility and viability of CAP vendors, we strongly recommend that approved vendors have a minimum of three years of experience in distributing Part B injectable drugs. Additionally, vendors must obtain 100% of their product supply from wholesalers that only acquire these products directly from the manufacturer. Based on shipping costs incurred for specialty products, we recommend a timeframe of 3-5 business days for a routine delivery. Flexibility in shipping timeframes allows CAP vendors to minimize shipping expenses when appropriate. We also recommend that CAP vendors be allowed to charge for next day shipping.

Licensure
Several state Medicaid programs and other coverage providers have restrictions that would prevent CAP vendors from submitting claims to secondary payers unless the vendor has a physical pharmacy location within the state. A CAP vendor should not have to obtain state-level pharmacy licenses or open specialty pharmacies in each state in order to participate as a CAP vendor on a national level. CAP vendors that are unable to complete secondary billing will have significantly higher uncollected balances that will then be shifted to the beneficiary. We recognize there will be some level of uncollectible accounts; however, we recommend that CMS provide waivers for applicable state licensure requirements to facilitate the appropriate billing of public and private payers on behalf of Medicare beneficiaries receiving services under the CAP.

3. CAP Bidding Process – Evaluation and Selection

Manufacturer Negotiation/Acquisition Costs
The viability of this program hinges on the ability of a CAP vendor to negotiate drug acquisition costs at lower levels than ASP. The ASP pricing mechanism represents a major change to the system that is still evolving. Our experience is that *many* Part B medications *cannot* be acquired today for less than ASP+6%. Manufacturers will be reluctant to extend any price discounts if CAP vendor sales are included in the ASP calculation as it would serve only to further drive down their effective sales price. Therefore, we strongly recommend that CMS:

1) raise the maximum allowable bid (ceiling) to the current payment rates or ASP+20%. Competitive market forces would result in savings to CMS and minimally acceptable prices for CAP vendors; or

2) exclude CAP vendor sales and distribution fees from ASP calculations by designating such sales as "Sales Exempted from Computation" in accordance with Section 1847A(c)2(B), which allows for "exception as the Secretary may otherwise provide."

In addition, CAP vendors should be exempted from the requirement to offer at least one product per billing category if the manufacturer of a single source item is unwilling to negotiate acquisition costs that are commensurate with ASP-based reimbursement. This exemption would provide a basis for manufacturer negotiations and would also protect the CAP vendor financially in the event that sales prices are reduced for all other purchasers.

As CMS proposes, we believe it is important for CAP vendors to be informed of the established price set for the CAP drugs prior to signing a contract. CAP vendors should have the opportunity to withdraw from the program at that time.

Inventory Management
As mentioned previously, McKesson is concerned about the financial risk for product that is lost, wasted, spilled or spoiled. We recommend that CAP vendors be allowed to include the estimated loss in the bid process by raising the overall allowable bid amount by 2%.

FDA Drug Removal
If the FDA removes a drug from the market, CMS should require re-weighting of the category for median price derivation.

Single Price Determination
McKesson is concerned that the historical utilization levels used in the composite bid process may be inaccurate under the CAP. Because physicians will no longer bear risk, they may be more likely to prescribe higher cost drugs for their patients. If actual utilization varies significantly from expectations, the single price determination process may not adequately reimburse a vendor's costs. McKesson recommends that CMS consider the implementation of risk corridors in the first three years to protect CAP vendors from significant variations in utilization.

After the first year, we recommend that the utilization levels used in the composite bid process be based on utilization specific to the CAP program. For drugs introduced after 2004, we recommend using year-to-date utilization levels of the new drugs to re-weight the category and determine a single price.

Acquisition Cost Disclosure
We strongly recommend weekly price adjustments, as currently occur under the Medicare drug discount card program, to reflect changes in marketplace pricing. CAP vendors could supply weekly *non-public* disclosures of net acquisition costs, as McKesson

currently provides to CMS under the Medicare-approved drug discount card program. We suggest that the price adjustments reflect actual adjustments to net acquisition costs, and not be subject to a threshold.

CMS includes a list of required documentation in support of net acquisition disclosures. While full disclosure and documentation of the vendor's acquisition purchases must be available upon request or audit, we recommend development of a streamlined format for submitting changes to acquisition costs to ease the administrative burden for CMS and for CAP vendors.

4. Contract Requirements

We strongly recommend that a CAP vendor be allowed to withdraw from the program at any time, rather than only once per year, if it can demonstrate a financial hardship, or if it can demonstrate that it cannot acquire product directly from manufacturers for less than the reimbursed amount. Upon submitting notification, a vendor should be allowed to withdraw after a 6 month period. Flexibility to withdraw from the program will encourage greater participation by CAP vendors.

D. Implementation of the CAP

1. Physician Election Process

CAP Vendor Selection
We support the proposal that CAP vendor election be made at the group practice level and recommend that it apply across group and private practice affiliations. CMS could facilitate and monitor such an election by requiring group practices to submit both group and individual UPIN numbers upon application. Without this requirement, physicians would be able to "cherry pick" medications to administer in their private practice, thereby requiring CAP vendors to supply a disproportionate share of the unprofitable drugs.

Program Departure of CAP Vendor
Physicians are currently accustomed to changing suppliers on a frequent basis. Therefore, it should not be problematic for them to select a different CAP vendor.

3. Beneficiary Education

McKesson would like to reinforce the importance of communication to beneficiaries on the CAP program, specifically regarding the new process for co-payment collection. CMS should create standard communication documents for physicians to provide to their beneficiaries, and require that physicians explain the payment process to their patients with signed in-office affirmation.

ALTERNATIVE PROPOSAL

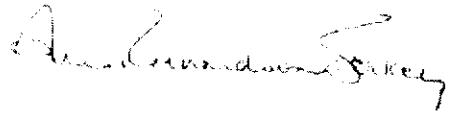
The risks associated with the proposed CAP could be mitigated if CMS bases the program on an alternative model that would cause fewer changes to the current reimbursement and distributive processes. Specifically, the procedures described for emergency replacement in the proposed regulations could be implemented for the entire program. By enabling a physician to use products from existing inventory, the inventory risks associated with the current model are significantly reduced. Additionally, physicians may be more likely to select the CAP if the program design enables them to maintain inventory control and ensure that the appropriate product is on hand for their patients. This alternative model would not alter the anticipated savings for the government.

CONCLUSION

McKesson was one of four companies that responded to an RFI from CMS and expressed interest in participating as a CAP vendor on a nationwide basis. We continue to support the efforts of CMS to create and implement a successful program. At the same time, we have concerns about the economic feasibility of a Competitive Acquisition Program as outlined in the proposed regulations. We have highlighted the challenges that may threaten the successful implementation of this program and have provided our recommendations for workable solutions. If these issues can be resolved, we look forward to supporting this program on a national basis.

Thank you for the opportunity to share our insights. Please do not hesitate to contact me at (415) 983-8494 or ann.berkey@mckesson.com should you have questions or need further information.

Sincerely,



Ann Richardson Berkey
Vice President, Public Affairs

Submitter : **Dr. Ray Page** **Date: 04/26/2005**

Organization : **The Center for Cancer and Blood Disorders**

Category : **Physician**

Issue Areas/Comments

1-15

Overview of the CAP

It is evident that the primary purpose of the CAP program is to save money for the Medicare program. By setting the bidding at ASP + 6 or below, CMS hopes to drive down its cost for drugs. CAP is also intended to serve as an alternative for physicians who wish to be relieved of the financial burdens associated with the drug acquisition business. The current ASP payment methodology used for drug reimbursement will necessitate the use of the CAP program for many physicians who are underwater on the majority of their drugs. The ASP model is a good concept but the method used to come up with ASP is flawed and has resulted in many physicians being unable to purchase many of their drugs at or below Medicare reimbursement. There needs to be a mechanism in place for addressing underwater drugs and therefore giving physicians a true ?choice? in whether they want to participate in CAP. CAP participation is currently a ?necessity? for some physicians and not a ?choice.?

There are still many unanswered questions regarding implementation, quality & service standards for vendors, and beneficiary education. These unanswered questions make it a huge risk for any physician to participate in CAP. Physicians are locked into the program for one year with no way out if the program fails to operate properly. There will be huge backlash from patients if this program fails. CMS needs to ensure that the vendor may not withhold drugs ordered by a physician for a patient for any reason.

Categories of Drugs to be Included under the CAP

Phase in - I believe that CMS should target a single specialty or small group before rolling CAP out in full force. While I realize the desire to target oncology for the potentially large savings along with providing a viable alternative for oncologists to acquire drugs, I urge CMS to be cautious in selecting a specialty that utilizes such a large volume of drugs. If there are problems with implementation it can have a damaging effect on patient access to care. My biggest concern is that no one (CMS, providers, vendors, beneficiaries) fully understands how this program is going to work and patients will be the ones to suffer. This is entirely new territory and there are still many unanswered questions in regard to implementation and quality. CMS needs to proceed with caution and not rush to implement this program on a broad scale without fully understanding how the process is going to work. As a provider, I see many problems with how to implement this program on our end and have concerns over the carrier?s ability to manage the complicated claims process.

Contracting Process-Quality and Product Integrity Aspects

The CAP program could negatively affect your most vulnerable patients. The vendor will not have an incentive to screen indigent patients for referral to patient assistance programs, thus creating a possible interruption in care and an undue financial burden to the patient.

Competitive Acquisitions Areas

The issue that vendors will not be required to offer more than one drug associated with a HCPCS code is of huge concern. While you may have different drugs within a single class, these drugs have different FDA approvals and indications and a patient?s response to one drug may be very different than another. Each person responds differently to a given drug. CMS is allowing a vendor to establish a formulary under CAP which is based on price and not quality. Patient access to certain drugs should not be limited based on CAP. Vendors should not be allowed to restrict access to drugs. Once a physician selects a vendor, that vendor should not be allowed to change the drugs they offer. If they are allowed this option, more physicians will be less likely to participate in this program due to added risk and uncertainty.

Doctors must select one CAP vendor to obtain all of their Part B drugs. Vendors would be required to supply a drug for each of the HCPCS J-codes identified, but in the case of multiple-source drugs, they would only be required to supply one manufacturer?s version. We may be forced to change a patient?s therapy based on drugs availability. These ?formularies? established by CAP vendors will be driven by price, not clinical effectiveness. Furthermore, if Least-Costly Alternative (LCA) is enforced, our physicians may not have access to all drugs and will be forced to change their patients? therapy and/or consider other treatment options.

CMS must allow physicians to purchase a drug and seek reimbursement under the ASP-based methodology if medical necessity requires a specific formulation to be administered to a patient and the vendor does not furnish that formulation.

Regional or state acquisition areas would most likely provide wider vendor participation. Physicians need to be able to obtain their drugs promptly from vendors. Smaller acquisition areas would assist in this. Vendors must be able to ship drugs 24-hours a day, 7 days a week. Approximately 1/3 of all regimens are changed on the day of treatment due to changes in the patient?s condition.

Claims Processing Overview

Increased administrative cost and burden having to track each drug and patient based on a prescription number. This burden begins with the pharmacy management, then moves to the nursing department, and ends with the billing and reimbursement department having to bill using the prescription number. CMS should compensate physicians for managing this process from rigid inventory control, to added paperwork and staff, and for program integrity.

In addition to filing all claims with Medicare for the drug?s administration, physicians will now have to include a new prescription number(s) with the claim. Currently, our billing programs are not designed to accommodate this number. In order to incorporate the required prescription number, we will have to incur the cost of purchasing new software or editing their existing program. Under the CAP program, claims must be submitted within 14 days of the date of service. Our billing office will need to change billing practices in order to accommodate this requirement.

The CAP vendor, not the physician, will file the claim with Medicare and receive payment for the drug. Providers must send patient information to the approved vendor for coinsurance collection. This means physicians will lose control over the collection process and the vendor may aggressively pursue the patient for co-

insurance collection. In many cases, patients may cease their treatment because they could not afford co-insurance.

Statutory Requirements Concerning Claims Processing

The enormous burden placed on physicians to participate in CAP without any compensation is unrealistic. Reimbursement for drug administration is still below the cost to provide the service and now CMS wants to add another administrative layer and cost to the process. The burdens include:
- Provider must submit a written prescription to the vendor for each patient treatment/drug (even though a provider writes an order for the entire course of treatment, there is nothing stating that the vendor must dispense it that way).
- Provider must include in their administration billing one or more prescription numbers necessary for the carrier to match the administration claim with the drug claim submitted by the vendor. This requires more data entry and cost on the billing end.
- Provider must notify the vendor when a drug is not administered. Again, another administrative layer and cost that does not currently exist.
- Maintain a separate drug inventory for EACH CAP drug.
- Required to provide information to vendor to assist in collection efforts against our patient. This is going to create a huge conflict between physician?s office and patient not to mention physicians want no part of collection agencies harassing their patients and causing added stress which only harms their health further.
These are all new administrative burdens the physician will have to take on that do not currently exist within the practice.

CMS needs to define ?emergency? as it relates to a physician having to justify the need to receive replacement drugs from their vendor to replace drugs taken from the physician?s inventory to treat a patient. The proposed rule requires that physicians justify the need to use drugs from their inventory by proving that they meet all of four criteria established by CMS. There is no room for human error built into this system. There will be instances where an office failed to order the drug out of oversight. This is not listed as an option that justifies using drugs out of the physician?s inventory. Under the buy-and-bill model physicians would just take the drug from their inventory and treat the patient. Under the CAP model, a patient?s treatment would have to be needlessly delayed because the CAP model does not allow a physician to use their own inventory in cases of oversight. A physician should be allowed to use stock.

GENERAL

GENERAL

If we were to participate in the CAP, our clinic will still incur all the costs with procurement, storage, inventory management, and disposal of drugs. With drugs received through the CAP, our pharmacy will need maintain a patient-specific inventory for each patient. We do not have the inventory system to accurately store the medication.
The regulations need significant clarification on handling unused drugs obtained through the CAP program. For example, in terms of disposing unused drugs, CMS should clarify whether the vendor is allowed to do anything with the unused drug that is permissible under state law or whether there any restrictions under the CAP or federal law that would apply.
To ensure quality and product integrity, vendors should be prohibited from opening drug containers and physicians should be permitted to return damaged or suspicious drugs.

Submitter : Mr. J. Melville Engle **Date:** 04/26/2005

Organization : Dey, L.P.

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-420-Attach-1.DOC

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April 26, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW.
Washington, DC 20201

Re: *Categories of Drugs to be Included Under the CAP*

Dear Sir or Madam:

Dey, L.P. is pleased to submit the following comments on a proposed rule issued by the Centers for Medicare & Medicaid Services (CMS) on a competitive acquisition program (CAP) for certain outpatient drugs and biologicals under Medicare Part B.[1]

Background on Dey and its Products

Dey, L.P. develops, manufactures, and markets prescription pharmaceuticals for the treatment of respiratory illnesses, including chronic obstructive pulmonary disease (COPD).

Dey's principal product for COPD is the FDA-approved DuoNeb® Inhalation Solution. DuoNeb® is a sterile, non-allergenic, premixed combination drug (ipratropium bromide and albuterol sulfate) that enhances safety by minimizing the risk of medication errors. Delivered by nebulizer, DuoNeb® eliminates the need for Medicare beneficiaries to nebulize two different solutions, resulting in faster treatment times and improved compliance.

Dey strongly supports efforts to bring higher quality care to Medicare beneficiaries, as well as greater cost consciousness to the Medicare program. Indeed, we are now working with CMS to help ensure that the new Part B pricing system based on Average Sales Price (ASP) truly captures the intended level of drug-related savings.

Overview of Comments

DuoNeb® is reimbursable under Medicare Part B's durable medical equipment (DME) benefit – specifically, as a drug furnished through DME. As such, Dey wishes to respond to the request made in the Proposed Rule for comments on the categories of Part B drugs to which CAP may permissibly be applied.

[1] Proposed Rule, "Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B," Centers for Medicare & Medicaid Services, 70 Fed. Reg. 10,745 (March 4, 2005) (hereinafter, "Proposed Rule").

Dey concurs in CMS's conclusion, as expressed in the Proposed Rule, that only physician-administered drugs should be subject to CAP. Moreover, as we explain below, provisions of the statute operate to specifically and affirmatively exclude DME inhalation drugs from CAP. Finally, even if CAP could somehow be construed to apply to DME inhalation drugs, we believe it would be impractical to include these drugs in the program.

Discussion

1. *Law Requires Exclusion of DME Inhalation Drugs from CAP*

a. *"Competitively Biddable Drugs and Biologicals"*

In the Proposed Rule, CMS noted that the pertinent provisions of the Medicare statute contain a defined term, "competitively biddable drugs and biologicals."[2] These are the drugs and biologicals that, under the statute, are made subject to CAP, beginning in 2006.[3]

This term "competitively biddable drugs and biologicals" is defined to mean all drugs and biologicals furnished on or after January 1, 2006, that *are not* described by any of three excluded categories of products.[4] The three excluded categories of products are certain vaccines;[5] infusion drugs furnished through DME;[6] and certain blood products.[7]

By virtue of its reading of this definition, CMS found that "competitively biddable drugs and biologicals" is broad enough to "include most drugs paid under Medicare Part B and not otherwise paid under cost-based or prospective payment basis."[8]

b. *Separate Provision Specifies Exclusive Basis for Part B Payments for DME Inhalation Drugs*

Despite the definition's apparent breadth, Dey believes that the applicable provisions of the Medicare statute, when considered as a

[2] *See* Social Security Act (SSA) §1847B(a)(2)(A).
[3] *See* SSA §1847B(a)(1)(A)(i). The statute also requires the Secretary of Health and Human Services to phase in CAP by such categories of competitively biddable drugs and biologicals as the Secretary shall establish. SSA §1847B(a)(1)(B).
[4] *See* SSA §1842(o)(1)(C) (42 U.S.C. §1395u(o)(1)(C)).
[5] *See* SSA §§1842(o)(1)(A)(iv) (42 U.S.C. §1395u(o)(1)(A)(iv)); 1861(s)(10)(A), (B) (42 U.S.C. §1395x(s)(10)(A), (B)).
[6] *See* SSA §§1842(o)(1)(D)(i), (ii) (42 U.S.C. §1395u(o)(1)(D)(i), (ii)); SSA §1847 (42 U.S.C. §1395w-3)).
[7] *See* SSA §1842(o)(1)(F) (42 U.S.C. §1395u(o)(1)(F)).
[8] Proposed Rule, at 10,749.

whole, clearly operate to exclude DuoNeb® and other DME inhalation drugs from the scope of CAP.

We note that it is a long-held rule of statutory interpretation that when two provisions of a statute potentially apply, it is the more specific of the two that controls. In this instance, there is a separate Medicare statutory provision dedicated solely to DME inhalation drugs that prescribes the basis upon which Part B will pay for those drugs, beginning in 2005. Specifically, this provision states that reimbursement for –

> "inhalation drugs or biologicals furnished through durable medical equipment . . . in 2005 and subsequent years [is] the amount provided under section 1847A . . ."[9]

Section 1847A, in turn, is the statutory provision that describes the ASP reimbursement methodology.

Thus, the provision quoted above, dedicated solely to DME inhalation drugs, is the more specific of the Part B payment provisions potentially applicable to these drugs. Because this more specific provision permits use of only the ASP-based reimbursement methodology, this methodology must be understood to be the exclusive means of Part B payment for these drugs. As such, the drugs cannot be subject to CAP.

In sum, while we agree with CMS's conclusion that CAP should be limited to physician-administered drugs, we also believe, as an additional fact, that the applicable statutory provisions operate to specifically and affirmatively exclude DME inhalation drugs from CAP's scope.

We therefore respectfully request that CMS's proposed regulatory definition of "competitively biddable drugs"[10] be amended by adding at the end the following clarifying sentence:

> "Such term does not include inhalation drugs or biologicals described in section 1842(o)(1)(G) of the Act."

2. *Practicality Requires Exclusion of DME Inhalation Drugs from CAP*

In the Proposed Rule, CMS identified a number of practical considerations that would impede inclusion within CAP of any drugs other than those that are physician-administered.

[9] SSA §1842(o)(1)(G) (42 U.S.C. §1395u(o)(1)(G)).
[10] *See* Proposed Rule, at 10,770 (proposing revised text for 42 CFR §414.902).

CMS pointed out that CAP is tailored to physician-administered drugs, observing that, "the specific mechanisms [for CAP] relate to the provision of and the payment for drugs provided incident to a physician's service."[11] To illustrate this point, the agency enumerated 9 separate examples of statutorily identified program features that appear to contemplate the sole participation of physicians, including the fact that "[o]nly physicians are expressly given an opportunity to elect to participate in the CAP."[12]

Dey supports the conclusion of CMS that CAP is properly limited to drugs that physicians administer. Physicians seldom administer DME inhalation drugs; thus, even if CAP could somehow be construed to reach DME inhalation drugs, the mechanics of the program could not practically or effectively be applied to these drugs.

Conclusion

For the reasons stated above, Dey supports the conclusion of CMS that only physician-administered drugs should be subject to CAP. Moreover, we believe that it would be inconsistent with statutory law, and with practical program implementation, to attempt to apply CAP to DME inhalation drugs.

We appreciate this opportunity to comment, and we look forward to continuing to work with CMS to help ensure high-quality, cost-conscious care for Medicare beneficiaries.

Sincerely,

J. Melville Engle
President and CEO

[11] *Id.*, at 10,749.
[12] *Id.*

Submitter : **Dr. Michael Ross** **Date: 04/26/2005**

Organization : **The Center for Cancer and Blood Disorders**

Category : **Physician**

Issue Areas/Comments

1-15

Overview of the CAP

It is evident that the primary purpose of the CAP program is to save money for the Medicare program. By setting the bidding at ASP + 6 or below, CMS hopes to drive down its cost for drugs. CAP is also intended to serve as an alternative for physicians who wish to be relieved of the financial burdens associated with the drug acquisition business. The current ASP payment methodology used for drug reimbursement will necessitate the use of the CAP program for many physicians who are underwater on the majority of their drugs. The ASP model is a good concept but the method used to come up with ASP is flawed and has resulted in many physicians being unable to purchase many of their drugs at or below Medicare reimbursement. There needs to be a mechanism in place for addressing underwater drugs and therefore giving physicians a true ?choice? in whether they want to participate in CAP. CAP participation is currently a ?necessity? for some physicians and not a ?choice.?

There are still many unanswered questions regarding implementation, quality & service standards for vendors, and beneficiary education. These unanswered questions make it a huge risk for any physician to participate in CAP. Physicians are locked into the program for one year with no way out if the program fails to operate properly. There will be huge backlash from patients if this program fails. CMS needs to ensure that the vendor may not withhold drugs ordered by a physician for a patient for any reason.

Categories of Drugs to be Included under the CAP

Phase in - I believe that CMS should target a single specialty or small group before rolling CAP out in full force. While I realize the desire to target oncology for the potentially large savings along with providing a viable alternative for oncologists to acquire drugs, I urge CMS to be cautious in selecting a specialty that utilizes such a large volume of drugs. If there are problems with implementation it can have a damaging effect on patient access to care. My biggest concern is that no one (CMS, providers, vendors, beneficiaries) fully understands how this program is going to work and patients will be the ones to suffer. This is entirely new territory and there are still many unanswered questions in regard to implementation and quality. CMS needs to proceed with caution and not rush to implement this program on a broad scale without fully understanding how the process is going to work. As a provider, I see many problems with how to implement this program on our end and have concerns over the carrier?s ability to manage the complicated claims process.

Competitive Acquisitions Areas

The issue that vendors will not be required to offer more than one drug associated with a HCPCS code is of huge concern. While you may have different drugs within a single class, these drugs have different FDA approvals and indications and a patient?s response to one drug may be very different than another. Each person responds differently to a given drug. CMS is allowing a vendor to establish a formulary under CAP which is based on price and not quality. Patient access to certain drugs should not be limited based on CAP. Vendors should not be allowed to restrict access to drugs. Once a physician selects a vendor, that vendor should not be allowed to change the drugs they offer. If they are allowed this option, more physicians will be less likely to participate in this program due to added risk and uncertainty.

Doctors must select one CAP vendor to obtain all of their Part B drugs. Vendors would be required to supply a drug for each of the HCPCS J-codes identified, but in the case of multiple-source drugs, they would only be required to supply one manufacturer?s version. We may be forced to change a patient?s therapy based on drugs availability. These ?formularies? established by CAP vendors will be driven by price, not clinical effectiveness. Furthermore, if Least-Costly Alternative (LCA) is enforced, our physicians may not have access to all drugs and will be forced to change their patients? therapy and/or consider other treatment options.

CMS must allow physicians to purchase a drug and seek reimbursement under the ASP-based methodology if medical necessity requires a specific formulation to be administered to a patient and the vendor does not furnish that formulation.

Regional or state acquisition areas would most likely provide wider vendor participation. Physicians need to be able to obtain their drugs promptly from vendors. Smaller acquisition areas would assist in this. Vendors must be able to ship drugs 24-hours a day, 7 days a week. Approximately 1/3 of all regimens are changed on the day of treatment due to changes in the patient?s condition.

Claims Processing Overview

Increased administrative cost and burden having to track each drug and patient based on a prescription number. This burden begins with the pharmacy management, then moves to the nursing department, and ends with the billing and reimbursement department having to bill using the prescription number. CMS should compensate physicians for managing this process from rigid inventory control, to added paperwork and staff, and for program integrity.

In addition to filing all claims with Medicare for the drug?s administration, physicians will now have to include a new prescription number(s) with the claim. Currently, our billing programs are not designed to accommodate this number. In order to incorporate the required prescription number, we will have to incur the cost of purchasing new software or editing their existing program. Under the CAP program, claims must be submitted within 14 days of the date of service. Our billing office will need to change billing practices in order to accommodate this requirement.

The CAP vendor, not the physician, will file the claim with Medicare and receive payment for the drug. Providers must send patient information to the approved vendor for coinsurance collection. This means physicians will lose control over the collection process and the vendor may aggressively pursue the patient for co-insurance collection. In many cases, patients may cease their treatment because they could not afford co-insurance.

Statutory Requirements Concerning Claims Processing

: The enormous burden placed on physicians to participate in CAP without any compensation is unrealistic. Reimbursement for drug administration is still below the cost to provide the service and now CMS wants to add another administrative layer and cost to the process. The burdens include:
- Provider must submit a written prescription to the vendor for each patient treatment/drug (even though a provider writes an order for the entire course of treatment, there is nothing stating that the vendor must dispense it that way).
- Provider must include in their administration billing one or more prescription numbers necessary for the carrier to match the administration claim with the drug claim submitted by the vendor. This requires more data entry and cost on the billing end.
- Provider must notify the vendor when a drug is not administered. Again, another administrative layer and cost that does not currently exist.
- Maintain a separate drug inventory for EACH CAP drug.
- Required to provide information to vendor to assist in collection efforts against our patient. This is going to create a huge conflict between physician?s office and patient not to mention physicians want no part of collection agencies harassing their patients and causing added stress which only harms their health further.
These are all new administrative burdens the physician will have to take on that do not currently exist within the practice.

CMS needs to define ?emergency? as it relates to a physician having to justify the need to receive replacement drugs from their vendor to replace drugs taken from the physician?s inventory to treat a patient. The proposed rule requires that physicians justify the need to use drugs from their inventory by proving that they meet all of four criteria established by CMS. There is no room for human error built into this system. There will be instances where an office failed to order the drug out of oversight. This is not listed as an option that justifies using drugs out of the physician?s inventory. Under the buy-and-bill model physicians would just take the drug from their inventory and treat the patient. Under the CAP model, a patient?s treatment would have to be needlessly delayed because the CAP model does not allow a physician to use their own inventory in cases of oversight. A physician should be allowed to use stock

Contracting Process-Quality and Product Integrity Aspects

CMS needs to establish guidelines for measuring quality and service performance standards for vendors. CMS needs to address issues related to shipment errors, counterfeit drugs, and timely delivery of drugs.

GENERAL

GENERAL

If we were to participate in the CAP, our clinic will still incur all the costs with procurement, storage, inventory management, and disposal of drugs. With drugs received through the CAP, our pharmacy will need maintain a patient-specific inventory for each patient. We do not have the inventory system to accurately store the medication.
The regulations need significant clarification on handling unused drugs obtained through the CAP program. For example, in terms of disposing unused drugs, CMS should clarify whether the vendor is allowed to do anything with the unused drug that is permissible under state law or whether there any restrictions under the CAP or federal law that would apply.
To ensure quality and product integrity, vendors should be prohibited from opening drug containers and physicians should be permitted to return damaged or suspicious drugs.

Submitter :

Date: 04/26/2005

Organization : **American Pharmacists Association**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

Please see attached.

CMS-1325-P-422-Attach-1.DOC

American Pharmacists Association

Improving medication use. Advancing patient care.

APhA

April 26, 2005

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1325-P
PO Box 8010
Baltimore, MD 21244-8010

Re: CMS-1325-P

Dear Sir/Madam:

Thank you for the opportunity to comment on the proposed rule implementing a competitive acquisition program (CAP) for certain Medicare Part D drugs and biologicals not paid on a cost or prospective payment system basis. The American Pharmacists Association (APhA), founded in 1852 as the American Pharmaceutical Association, represents more than 52,000 practicing pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in advancing the profession. APhA, dedicated to helping all pharmacists improve medication use and advance patient care, is the first-established and largest association of pharmacists in the United States.

The proposed rule provides for an alternative to the current payment methodology for the limited number of drugs and biologics available under Medicare Part B. Currently, Part B drugs and biologicals not paid on a cost or prospective payment basis are reimbursed at 106% of the Average Sales Price (ASP). Under the proposed rule, which implements changes mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the Act), physicians would have the option to continue purchasing and seeking reimbursement for Part B drugs as they do now, or obtaining these drugs from a vendor selected through a competitive bidding process.

APhA recognizes the Centers for Medicare and Medicaid Services' (CMS) desire to provide an alternative payment system for Part B drugs. The creation of the competitive acquisition program is part of Congress' and CMS' continuing efforts to implement an "appropriate" reimbursement system for Part B drugs. Since passage of the Act in 2003, the reimbursement system has been revised twice: first moving from 95% to 85% of the Average Wholesale Price (AWP) in 2004, and then moving from AWP to 106% of the Average Sales Price (ASP) in 2005. With the introduction of the CAP in 2006, CMS hopes that the ASP and CAP payment methodologies will more accurately reflect actual product costs. The CAP system is expected to benefit the Medicare program, because as the Agency states in its proposed regulation, the program will only accept bids that fall below the payment level of 106% of the ASP which should result in lower reimbursement costs for the Medicare program. Although APhA

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supports efforts to revise the system to more accurately reflect product costs and the costs to provide the product, we have several concerns with the program as currently proposed.

Categories of Drugs to be Included under the CAP

The statute limits the competitive acquisition program to Medicare Part B drugs administered incident to a physician's service, drugs administered through durable medical equipment (excluding infusion drugs), and some drugs usually dispensed through pharmacies. The preamble of the rule contains a discussion on the categories of drugs that should be included in the CAP. According to the preamble, the Agency is considering whether all drugs allowed by statute should be included in the program, or if the program should be limited to drugs provided incident to a physician's services. The Agency also questions whether the CAP should be implemented incrementally, such as initially only allowing drugs administered by one type of physician specialty into the program.

The Agency should limit CAP drugs to those provided incident to a physician's services. Part B drugs that are administered by a physician or incident to a physician's services are appropriate medications for the competitive acquisition program. However, oral Part B drugs that are typically obtained from an outpatient pharmacy and self-administered should not be included in the program, as there would be little benefit in including oral Part B medications in the CAP. The very structure of the CAP would only increase the complexity and cost of paying for drugs administered orally. Increased costs include those costs associated with shipping the product from the pharmacy or other vendor to the physician. The program will also create delays for the patient to obtain the medication, as well as contradict the Medicare program's freedom of choice provision that protects beneficiaries' ability to secure services (such as oral Part B drugs) from the provider of their choice. If there is no need for the physician to administer the product, the product should be excluded from the CAP.

APhA also recommends that the Agency implement the CAP in stages. By implementing the program incrementally, the Agency will have the opportunity to examine the program's operation and make any necessary revisions before the program is expanded to all physicians and all CAP eligible products.

Competitive Acquisition Areas

The MMA directs the Secretary of the Department of Health and Human Services to establish competitive acquisition areas in which vendors may bid to supply Part B drugs. The proposed regulation does not establish those areas, but requests comments on how the areas should be determined. According to the regulation, CMS is considering several options: establishing state-wide areas, establishing a number of regional areas, or establishing one national area. APhA supports the establishment of state-wide competitive acquisition areas. We are concerned that the establishment of national or regional levels would make it difficult, if not impossible, for smaller pharmacies and other suppliers to participate as CAP vendors. With fewer vendors able to compete on a regional or national level, physicians will have fewer CAP vendors to select from and competition among the vendors will decrease. A nationwide or regional area would also present licensing problems. To participate in a regional or national area, vendors would be required to obtain a license in each state in which they deliver drugs. This would be a significant undertaking if the Secretary establishes one national competitive acquisition area. Pharmacies and other drug distributors are licensed on a state level; therefore, state-wide acquisition areas seem most appropriate. State-wide acquisition areas will also allow a greater number of pharmacies to participate in the CAP and encourage competition. A state-based system would not prevent bidders who wish to provide CAP drugs in multiple regions or nationwide from submitting multiple bids to do so.

Claims Processing Overview

The proposed regulation contains an overview of the claims processing system for drugs obtained through the competitive acquisition program. According to the regulation, after selecting a CAP vendor, physicians will order Part B drugs needed for specific patients from the vendor. When the vendor receives the order from a physician, the vendor will assign the order a prescription number and ship the drug to the physician. The CAP vendor will then submit a claim for the cost of the drug product to the designated Medicare carrier, which will reimburse the vendor after verifying that the physician has administered the drug to the patient. The carrier will verify administration of the product by matching the prescription number on the vendor's claim for the drug product to the prescription number on the claim submitted by the physician for the cost of administering the drug. The vendor will then bill the patient for any applicable deductible or co-payment for the drug.

According to CMS, this process will benefit physicians by saving time, reducing paperwork, and decreasing financial burdens associated with physician purchasing of drugs.[1] While APhA supports efforts to decrease administrative burdens for providers, we are concerned that the regulation claims to simplify the drug acquisition and reimbursement process, when it simply shifts the administrative and financial burden from one provider (the physician) to another (the pharmacist or other vendor). Pharmacies that participate in the CAP will be responsible for taking prescription orders from physicians, assigning prescription numbers, shipping the drug, estimating when the drug has been administered and it is "safe" to submit the drug claim, and determining when it is appropriate to bill the beneficiary for the deductible or copayment and the applicable amount.

The proposed claims processing system is far more complex than the current reimbursement system for Part B drugs. For example, the pharmacy cannot submit a claim for the drug product until the drug has been administered by the physician. How will the pharmacist know that the drug has been administered? While CMS can request that physicians administer the drug within two weeks of receipt of the drug, the physician is not required to do so. The pharmacist will not be able to determine if the drug has been administered unless they contact the physician, or submit the claim two weeks after the drug product was delivered and hope that it has been administered so the claim will be filled.

The proposed claims process may also result in lengthy delays between the time the pharmacy supplies the physician with the product and the time the pharmacy is reimbursed. Consider what would happen if a physician decides not to administer a product after it has been delivered. The pharmacy could not bill Medicare for the product since it was not administered. According to the regulation, the vendor and physician would be expected to "reach an agreement on how to handle the unused drug" which may include allowing the drug to remain in the physician's drug inventory – which will be the only option in states that have limits on product returns to the supplier. When the drug was eventually administered to another Medicare beneficiary, the pharmacy would assign a new prescription number to the product and submit a reimbursement claim.[2] This would create an untenable situation for many pharmacies. Pharmacies already operate on a small profit margin, they cannot supply product with no real assurances when, if ever, they will be reimbursed.

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[1] Centers for Medicare and Medicaid Services. Press Release. "CMS Proposed New Program for Physician Administered Drugs: Proposed Rule Could Ease Burden on Physicians." February 25, 2005.
[2] 70 FR at 10756.

A similar situation could occur when the pharmacy bills the beneficiary for the applicable deductible or coinsurance amount after the Medicare carrier approves the pharmacy's drug product claim. What happens if the beneficiary fails to pay the pharmacy? The beneficiary has little incentive to pay – the beneficiary has already received the product – or the beneficiary may decide they are unable to afford the coinsurance. The pharmacy's only option would be to keep pursuing payment from the beneficiary or refuse to supply further products for that beneficiary until the bill has been paid.

APhA requests that CMS reconsider the proposed claims system for CAP products. Pharmacies or other vendors should be able to bill the Medicare carrier for the drug product at the time of delivery to the physician. When the pharmacy delivers the product to the physician, the pharmacy has fulfilled its responsibilities; it has dispensed a prescription order by the physician for a specific patient. Like any other retail transaction, payment should be due upon receipt of the product, not the first time the product is actually used. If the pharmacy is not allowed to bill for the full cost of the drug product at the time of delivery, the Agency should, at a minimum, allow the pharmacy to seek partial payment from the Medicare carrier when the product is shipped. The Medicare carrier could reimburse the pharmacy for the remaining amount upon receipt of the physician's claim for administration services.

As we stated earlier, oral Part B drugs that are typically obtained from an outpatient pharmacy and self-administered, should not be included in the CAP. However, if these products are included, CMS must include the supplying fees that pharmacies currently receive for certain Part B drugs such as immunosuppresives. These separate fees were created by the Act to more appropriately compensate pharmacies for the costs incurred and the services provided when supplying certain Part B products. The fees were designed to balance the reduction in reimbursement for the actual drug product. Based on the Agency's discussion of the bidding process in the proposed rule, we anticipate that reimbursement costs for the drug product will be as low, if not lower, than the current reimbursement rates under 106% of the ASP. With low reimbursement rates under the CAP, pharmacies will require a similar supplying fee as reimbursement for the costs associated with supplying Part B drugs under the competitive acquisition program. We request that the Agency clarify that those supplying fees will be included in the final regulation if these drugs are included in the CAP.

On a related issue, the regulation states that vendors will include the physician's unique provider identification number (UPIN) to identify the physician on claims submitted to the Medicare carrier. We question why the regulation lists the UPIN as the provider identifier. Under the Health Insurance Portability and Accountability Act of 1996, the majority of providers are required to obtain a National Provider Identifier (NPI) that will serve as a unique identifier in transactions with Medicare, Medicaid, and private payors. Providers can begin applying for a NPI this May. APhA recommends that CMS use the NPI as the provider identifier for claims submitted under the CAP. If the NPI enumerator is unable to fulfill all requests for a NPI prior to January 1, 2006, the Agency could temporarily allow providers to use the UPIN until their NPI is available.

Contracting Process – Quality and Product Integrity Aspects / Bidding Entity Qualifications

The proposed regulation contains a discussion of the requirements a pharmacy or other supplier must meet in order to obtain CMS approval as a CAP vendor. Among the qualifications are "quality, service, financial performance, and solvency standards" and "adequate administrative arrangements… to ensure effective operations."[3] APhA agrees that CAP vendors should be required to meet certain standards to

[3] 70 FR at 10758 and 10760.

ensure that physicians and beneficiaries receive quality Part B products in the manner envisioned by the Agency. We would welcome the opportunity to evaluate and respond to the proposed vendor requirements; however, the requirements listed in the regulation are vague and nonspecific. Until the requirements are better defined, we are unable to provide comments. The Association requests that CMS revise the regulation to include specific requirements that pharmacies and other suppliers must meet in order to qualify as a CAP vendor, and allow comments at that time.

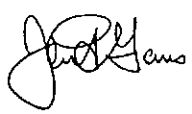
Regulatory Impact Analysis

The proposed regulation contains a brief discussion of the regulation's impact. The impact analysis concludes that the regulation "would have an impact on entities, either existing or formed specifically for this purpose, that are involved in the dispensing of drugs."[4] In other words, the regulation will impact pharmacies. The analysis contains to state that, "This impact would be dependent on the categories of drugs and geographic areas that are determined to fall under the CAP and on their ability to successfully compete and receive approval as a vendor under the competitive acquisition program."[5] We agree with the Agency's determination that the regulation will affect pharmacies and other drug suppliers. The impact on pharmacies that currently supply Part B drugs could be significant. We are, however, disappointed that the Agency's analysis of the impact on pharmacies stops there. Although the regulation states that pharmacies will be affected, the regulation does not provide any additional information on how they will be affected.

We urge CMS to further examine how the competitive acquisition program will impact pharmacies and the patients they serve. If the design and requirements of the regulation prevent pharmacies from participating in the program, the effects will extend far beyond the pharmacies. A lack of participation by pharmacies will reduce competition among vendors and decrease the number of vendors that physicians can select from, and may negatively affect beneficiaries' access to Part B medications. We offer our assistance to the Agency as it works to define CAP vendor requirements and further develop the program.

Thank you for your consideration of the views of the nation's pharmacists. Please contact Susan K. Bishop, Associate Director, Regulatory Affairs at 202-429-7538 or SBishop@APhAnet.org with any questions.

Sincerely,



John A. Gans, PharmD
Executive Vice President

cc: Susan C. Winckler, RPh, Esq, Vice President, Policy & Communications and Staff Counsel
Susan K. Bishop, MA, Associate Director, Regulatory Affairs

[4] 70 FR at 10768.
[5] Ibid.

Submitter : **Joe Zuraw** **Date: 04/26/2005**

Organization : **Talecris Biotherapeutics**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-423-Attach-1.TXT

[redacted]

Talecris

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May 3, 2005

Mark McClellan, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Submitted electronically to:
http://www.cms.hhs.gov/regulations/ecomments

File Code: CMS-1325-P
Categories of Drugs To Be Included Under The CAP

Dear Administrator McClellan:

Talecris Biotherapeutics, Inc. (Talecris) appreciates the opportunity to submit these comments regarding the Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B Proposed Rule, 70 Fed. Reg. 10745 ("Proposed Rule").

About Talecris and Our Biological Products

Talecris is a new company that acquired the contributed assets of Bayer Biological Products' plasma business, including the immune globulin intravenous (IGIV) product Gamunex®, Immune Globulin Intravenous (Human), 10% - Caprylate / Chromatography Purified and the Alpha 1 proteinase inhibitor (A1PI) product Prolastin®, Alpha1 Proteinase Inhibitor (Human). Gamunex® supplies a broad spectrum of antibodies for the prevention or attenuation of a wide variety of infectious diseases and treats many immune deficiencies. Prolastin® is used in the treatment of Alpha 1 antitrypsin deficiency, also known as AAT, which is the most prevalent fatal genetic disorder of adult Caucasians in the United States.

I. Congress Intended to Exclude IGIV and A1PI from CAP

Within the Medicare Modernization Act, Social Security Act section 1842(o)(1)(E)(ii) creates a distinct, specified payment formula for IGIV even though the payment amount for 2005 and beyond is similar to most other Part B drugs and biologicals, i.e. 106% of Average Sales Price. We believe Congress' intent with that language was to remove IGIV from any payment program other than Average Sales Price -- the one contained in section 1847A of the Social Security Act which is referenced in section

[redacted]

Talecris

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1842(o)(1)(E)(ii). If the statute is unclear in its purpose, the Conference Report should remove any doubt. "Competitively biddable drugs and biologicals exclude . . . IVIG products and blood products." [1]

Although not specifically mentioned by product class, A1PI is a "blood product" and also comes under the intent of the Conference language.

Based on the clear directive of the Conference Report, the Secretary should exclude IGIV and A1PI from CAP.

II. CAP Proposal Creates Access and Safety Risks for Patients Who Need Plasma-Derived Therapies Such As IGIV and A1PI

The Proposed Rule states that CAP contractors would not be required to provide every National Drug Code (NDC) associated with a HCPCS code (at p.10751). For plasma products such as IGIV and A1PI, this raises potentially significant access and safety issues that are discussed below.

A. Issues Related to Access

The manufacture of plasma-derived biologicals, including IGIV and A1PI, is subject to variables that can limit product availability at a given point in time. Product shortages occur periodically because of inadequate supply of raw material (pooled plasma), limitations in production capacity or failure of finished product to be cleared for marketing by the Food and Drug Administration.

Those responsible for maintaining inventory of these biologicals are acutely aware of the potential for shortage. As recently as April 2005, in a supplement to *U. S. Pharmacist*, two pharmacy directors caution that for IGIV, "Pharmacists should plan for potential shortages by establishing an emergency supply and minimizing waste." [2]

If CAP vendors are allowed to contract for only one specific product for a HCPCS code that describes several plasma products, physician and their patients are at risk that a shortage of the contracted product can quickly become an access crisis for them. Manufacturers and distributors of other products may not be able to supply the CAP physicians because existing customers' needs must be met before new customers are accommodated.

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B. Issues Related to Safety

The fact that HCPCS codes for IGIV and A1PI describe multiple products suggests that the products are always therapeutically interchangeable. There is no evidence to support that conclusion and, in fact, there is ample evidence that product differences are clinically significant in elderly patients and those with other risk factors.

IgG antibodies are the active ingredient in all IGIVs; however active ingredient alone is insufficient to evaluate differences among IGIV products.

Differences among IGIV products relate to differences in their *biologic activity*. Biologic activity, which is altered by the manufacturing process, the method of viral inactivation and certain IGIV components, has significant clinical implications in the treatment of some patients. Furthermore, different manufacturing steps affect product characteristics that impact tolerability, such as formulation (liquid or powder), concentration, sugar content, sodium concentrations and osmolality.

In the April 2005 supplement to *U. S. Pharmacist* previously referenced, Schleis and Siegel write, "With IGIV being used to treat patients with a variety of disorders, pharmacists need to be aware that all IGIV products are not alike. Differences in product composition, efficacy, tolerability, safety, packaging, convenience, and economics translate directly into both positive and negative effects on both patients and health care providers."[2]

Currently available IGIVs vary in terms of available formulation, concentration, and osmolality as well as the final pH. Products also contain varying amounts of sodium and sugars. Some IGIV preparations contain sugar as a stabilizer; others do not. For a comprehensive comparison of IGIV products please see "Table 1 – Therapeutic Considerations" in the attached 2004 *Pharmacy Practice News* Special Edition entitled, "Intravenous Immune Globulins: Therapeutic, Pharmaceutical & Cost Considerations." [3]

Because of the differing characteristics, certain products may not be well tolerated by or recommended for particular patient populations. Additionally, individual patient tolerability may differ between certain products. In a February 2005 review of IGIV therapy in primary antibody deficiency disease,[4] Durandy, Wahn, Petteway and Gelfand write that, "... [M]any aspects among the available products do differ when duration of the manufacturing process to isolate IgG, the methods of viral inactivation and removal and the final composition, sugar, salt and osmolality are compared. Differences in clinical efficacy among the different products may also be present." (at p.228)

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The authors also state, "It is important to define which patients may be at higher risk for developing a significant adverse event. In principle, elderly patients, diabetics, those with impairment of cardiac or renal function, hypovolemia and a predisposition to clotting abnormalities should be identified and an IGIV product selected that does not add to or compound this risk." (at p. 224) Finally the authors conclude, "***Given the needs or risks of certain patients and these IGIV differences, it is important to match patient risk factors with IGIV risk factors.***" (at p. 228)

Comparable issues of product variance present for A1PI augmentation therapy. Though not as well documented in the literature as IGIV differences (perhaps because there are many fewer patients taking A1PI than IGIV and, until 2003, there was only one A1PI product marketed in the U.S.), clinically differences in tolerability should be presumed until all doubt is removed. The A1PI products are single source plasma protein therapies that are *not* rated as therapeutic equivalents in the Orange Book and have *not* otherwise been found to be pharmaceutically equivalent or bioequivalent to one another by the FDA.

An example of FDA caution in this area can be found in a current FDA investigation of reported variances in A1PI augmentation therapy. For a description of the issues, please see *Alpha-1 News*, vol. 16, no.1 March 2005 at pp.16-17, available at http://www.alpha1.org/news/newsletter.asp

Until the FDA has concluded its inquiry, we suggest that it would be premature to presume that one A1PI product could safely and effectively serve the medical needs of all Alpha-1 patients.

III. Conclusions and Recommendations

- Congress intended to exclude IGIV and A1PI from the Competitive Acquisition Program and clearly expressed that intention in the Conference Report.

- The manufacture of plasma-derived biological products requires a supply of raw material that can be interrupted with little warning due to factors that are outside the manufacturers' control.

- FDA approval of individual lots create an additional reason why, despite manufacturers' best efforts, a given plasma product may not be available in adequate quantity to meet all medically necessary requests for that product.

[redacted]

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- Not withstanding the fact that one HCPCS code is assigned to several different plasma products within the same class of biological, there are clinically significant differences among products within the class. Researchers and clinicians have concluded that as patient risk factors increase, the clinical significance of those differences increase.

- Because of these access and safety issues, CAP guidelines that allow contractors to supply only one or two selected plasma products within a class will put Medicare patients who rely on these life saving products at significant risk.

➢ **For the reasons stated above, CMS should exempt IGIV, A1PI and other plasma-derived biological products from CAP.**

Respectfully submitted,

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References

1 H.R. Conf. Rep. No. 108-391, at 593.

2 Schleis T, Siegel J: Formulary Considerations for IGIV Products. US Pharm 2005 Supp.

[redacted]

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3 Siegel J: Intravenous Immune Globulins: Therapeutic, Pharmaceutical & Cost Considerations. Pharm Prac News 2004 special edition.

4 Durandy A, Wahn V, Petteway S, Gelfand E: Immunoglobulin Replacement Therapy in Primary Antibody Deficiency Diseases – Maximixing Success. Int Arch Allergy Immunol 2005; 136:217-229.

Submitter : Mrs. Alice Pickering **Date:** 04/26/2005

Organization : Coastal Cancer Center

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachement

CMS-1325-P-424-Attach-1.DOC

April 25, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8010
Baltimore, MD 21244-8010

Attention: CMS-1325-P

To Whom It May Concern:

Thank you for the opportunity to comment about RX CAP. I am grossly concerned about RX CAP. I do not understand why we are getting a government directed program when we have a drug delivery system that works. To me, that is a proven statement because during 9-11, even without planes to deliver the drugs, all of our drug delivery continued flawlessly.

Where I do believe that reimbursement for chemotherapy agents does need change, I do not believe that CAP is the answer. Eighty-four percent of cancer patients are treated in community cancer centers and I feel there will be administrative burdens and costs even if a provider chooses to go with CAP; such as, if the patients cannot get their chemotherapy or treatment is delayed because of low counts or the doctor needs to change their regimen. Also the tracking would be burdensome and costly having a specific drug prescription number for each CAP drug.

Some other problems would be keeping a separate inventory of each CAP drug, notifying vendors when a drug is not administered on the expected date, and billing in 14 days. Last, but not least, I am concerned that trying to meet all the requirements that CAP imposes will detract from actual patient care. Again, these are just some of my concerns and I do not feel as if CAP is a realistic solution

I appreciate the opportunity to voice my concerns regarding the CAP Rule.

With kindest regards,

Alice Pickering,
Administrator

cc: Senator Lindsay Graham
Senator Jim DeMint
Representative Henry Brown

Submitter : Joe Zuraw **Date:** 04/26/2005

Organization : Talecris Biotherapeutics

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Attached are the references for Comment Number 16157

CMS-1325-P-425-Attach-1.TXT

CMS-1325-P-425-Attach-2.PDF

Note: CMS did not include the attachment(s) to this comment due to copyright restrictions.

Submitter : **Ms. Patricia A. Kaden** **Date: 04/26/2005**

Organization : **Medical Oncology Associates of Long Island**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

As an administrator of a four-physician community oncology practice, I have serious concerns regarding the implementation of the proposed CAP program. Although I will further comment on specific areas, in general, I believe it will compromise patient care, as well as access to that care,impose additional costs,liability and administrative burden on the community oncology clinics and, ultimately, cost Medicare more money.
My specific concerns on the CAP program, as currently structured, are as follows:
1. Patients and their caregivers will be inconvenienced by having to return for treatment because drugs will have to be ordered. This results in pain and suffering for the patient, lost job time for the caregiver and increased cost.
2. What will happen to the patient who cannot pay the resultant co-insurance for treatment? Will the pharmacy vendor carry or forgive that bad debt as we sometimes must, or will they stop drug delivery for that patient?
3. Integrity of drugs being shipped and to where, as well as management of multiple inventories becomes another nightmare.
4. Being "locked into" a drug vendor for an entire year, regardless of service, is not exactly a model of good business practices.
5. Software and billing programs must be changed, again an expense, but also lack of leadtime to accomplish presents yet another issue.

It is our strong belief that if CMS were to fix the current drug payment system to ASP+12%, with adequate administration reimbursement, coupled with annual review of costs and payments, we would not need CAP.

Submitter : Dr. JAMES H. SCULLY **Date: 04/26/2005**

Organization : THE AMERICAN PSYCHIATRIC ASSOCIATION

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT

CMS-1325-P-427-Attach-1.DOC

April 28, 2005

Mark McClellan, M.D., Ph.D., Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-P
P.O. Box 8010
Baltimore, MD 21244-8010

RE: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B"
CMS-1325-P

Dear Administrator McClellan:

The American Psychiatric Association (APA), the national medical specialty society representing more than 35,000 psychiatric physicians, nationwide, appreciates the opportunity to submit these comments concerning the proposed rule for acquisition of drugs and biologicals, under 42 C.F.R. Part 414, published in the Federal Register on March 4, 2005, with the title, "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B"[1]

APA appreciates the burdens attendant to the drug and biologicals acquisition process that psychiatrists and other physicians have used thus far and generally supports CMS' stated goal of relieving some of those burdens. However, there are specific aspects of this proposed competitive acquisition process that will substantially impact APA members in an adverse manner. One primary problem resides in the numerous, burdensome, time-consuming administrative requirements imposed upon physicians who elect to participate in CAP.

A second major problem is CMS' proposed dispute resolution system for vendors in this federal program. CMS inappropriately proposes, to the substantial disadvantage of physicians, to shift the initial administrative discovery and adjudication process from a neutral federal adjudicative body, which ordinarily handles such matters, to a biased, private insurance carrier with a fiduciary duty to the vendor and business interests contrary to those of the

[1] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)].

physicians. The process is ostensibly set up for vendors to resolve disputes, but it does not even require an actual dispute to be initiated. It essentially moves physicians, for some purposes, out of the Medicare Part B adjudicative process, which is the physicians' avenue of redress. It does so by placing first-level administrative adjudicative authority, as to issues of physicians' compliance with legal obligations under CAP, into the hands of the vendor's private carrier, which whom CMS contracts to process vendors' claims. The vendor can initiate this process at will and in absence of any criteria, other than some unspecified percentage, number or amount of unreimbursed vendor's claims. Moreover, CMS proposes that the vendor's carrier, at the request of the vendor, should have the authority to recommend a physician's suspension from CAP. Details regarding these issues and other concerns are outlined in the comments, below.

It is essential that this CAP process be implemented in line with CMS' stated goal of making it easier for physicians to handle drug acquisitions and treat their patients, rather than imposing complexities that have the opposite effects. To enhance patient access to them, APA supports inclusion of psychotherapeutic medications in the initial drug categories to be offered under CAP, especially long-acting, injectable anti-psychotic drugs. As proposed, the CAP system contains substantial deterrents to adoption by the physician community. However, many of these problems are subject to simple corrective measures, as APA will recommend within these comments. Following CMS' lead, use of the word "drugs" herein will comprise both drugs and biologicals under CAP.

I. CAP Drug Categories and Vendors

A. CAP Participation ("Physician Election Process")

Currently, a physician can directly purchase Medicare Part B-covered drugs from one or more vendors, then get reimbursed by Medicare for the drugs, under the Average Sales Price (ASP) system. Reimbursement rates are based on 106% of the ASP of the drug. For single-source drugs, Medicare pays 106% of the wholesale acquisition cost (WAC).[2] The Competitive Acquisition Process (CAP) is designed to provide an alternative to ASP. The stated intent of CAP is to alleviate the burden on physicians to expend money to purchase drugs, have capital tied up in drug inventories until they administer the drugs to patients, then make claims for and wait for Medicare drug reimbursements. This method impedes cash flow and reimbursement times can be unpredictable. The time span between expenditures for drug inventories and reimbursement for them especially impacts practices where the margin of extra capital is narrow. Typically, this is true of physicians in solo practices, small groups and in community mental health clinics, the three settings which comprise most of APA members' psychiatric practices.

Under CAP, physicians order drugs from vendors, who deliver the drugs directly to physicians' offices. Vendors will claim drug reimbursements from a designated carrier

[2] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42]; at 10748.

and physicians will claim reimbursements for drug-administration services from a local carrier. Vendor reimbursement will occur, upon verification that a physician administered the drug, through approval of the physician's claim and matching the prescription numbers of the vendor's and physician's claims.

CMS proposes that the physician CAP election process will run from October 1st to November 15th of each year. At any time during this period, the physician can choose whether or not to elect CAP participation and choose the vendor(s) to which s/he is exclusively committed for drug purchases within chosen categories. For this first year in 2005, CMS' initial website posting of vendors and pertinent information is anticipated to start October 1st. CAP election agreements must be postmarked by November 15th but the carrier is not expected to be ready to pay claims until January 1, 2006. That means that the earlier a physician elects CAP and acquires drugs from CAP, the longer the physician will wait for reimbursement for drug administration. The time lag will be over three months for those who elect early. This delay in payment is especially onerous for solo and small group practitioners, which are how the bulk of APA member psychiatrists practice. There will be a substantial financial disincentive to commit to a program under which a physician cannot anticipate payment for months.

CMS did not address this time gap that works against physicians' interests. One remedy would be to permit physicians to complete the CAP election process, with the agreement effective as of January 1, 2006, and allow them to use ASP until then. This would start the CAP commitment only when the claims payment process is actually available, thus avoiding the initial payment delays.

Recommendation- Physician Election Process: APA urges CMS to allow physicians to avoid payment delays from the initial 2005 CAP enrollment process by permitting physicians to complete the CAP election process, with the agreement effective as of January 1, 2006. They could use ASP until then.

B. Psychotropics should be Included in CAP Categories at the Outset ("Categories of Drugs to be Included under the CAP")

CMS intends at this time for CAP to only include "competitively biddable" Medicare Part B-covered drugs that are administered "incident to a physician's service," though CMS acknowledges that the statute provides a "potentially broader definition" for which types of drugs may be covered.[3] Drugs furnished "incident to a physician's service" refers to drugs that are usually not self-administered by the patient. Instead, a physician administers them to the patient. Injectable drugs are an example. For psychiatrists, one such drug is risperidone, a long-acting anti-psychotic targeted for schizophrenia that is available in a long-acting formulation within an injectable delivery system that requires a physician's administration; other anti-psychotic medications

[3] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10749.

psychiatrists use include haloperidol decanoate and fluphenazine decanoate.[4] Long-acting injectable anti-psychotics are the treatment of choice for many patients, especially because they can help stabilize psychotic patients for whom oral medication compliance is a particularly difficult issue. However, this form of drug may be prohibitively costly to inventory under ASP for psychiatrists with little available cash flow, including those in community mental health clinics. If CAP can overcome the financial barriers to access of injectable anti-psychotic drugs, it can be extremely beneficial to many psychiatric patients.

To the extent that a physician can obtain the Part B-covered drugs needed for a given practice, the CAP election may be more attractive than ASP. Unlike physicians who may use drugs of many types to treat a large spectrum of illnesses, psychiatrists typically use a relatively small group of medications, notably anti-depressants, anti-psychotics, sedatives, and stimulants. This is also true for many specialty physicians, who use a smaller spectrum of drugs routinely, than do general physicians. This is why APA advocates that CMS include drug categories for all major specialty groups, including psychiatrists, in the initial CAP offerings, as this would provide the incentive for a much larger number of physicians to elect CAP at the outset. Unless CAP drug categories include psychotherapeutics, psychiatrists, who are a sizable physician specialty group, would have no reason to elect CAP. A large component of APA members are in solo or small group practices, so their cash flow is not such that it is easy for them to fund drug inventories and wait for drug reimbursements under ASP. Provided that the drugs they need are available, CAP may prove to be a better financial choice than ASP for psychiatrists who acquire drugs to administer to patients in their offices or clinics. For community mental health clinics that are typically under-funded, CAP may provide welcome financial relief.

Recommendation- Include Psychotherapeutics in Initial CAP Category: APA believes that it is imperative that psychotherapeutic drugs be included in whatever initial category or categories CMS adopts for CAP, so that psychiatrists and their patients can enjoy the benefits of the program, including increased access to psychotropic drugs, especially long-acting injectable anti-psychotics, as soon as possible. APA supports inclusion of drug categories used by all major physician specialty groups in the initial CAP offerings.

C. Drug Categories and Vendors' Disclosure of National Drug Codes

During the bidding process for the CMS contract, vendors must disclose to CMS the National Drug Codes (NDCs) that specify the manufacturer of a drug listed by its generic chemical name under the HCPCS code that appears within a CAP category.[5]

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[4] "RISPERDAL CONSTA (risperidone) Long-Acting injection is a proven medication with a state of the art delivery system that gives you the same medicine as RISPERDAL (risperidone) pills, but in a form that is given every 2 weeks. RISPERDAL CONSTA can help reduce the positive and negative symptoms that are part of schizophrenia. . ." Retrieved April 13, 2005: http://www.risperdalconsta.com

[5] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10751.

This disclosure should be transparent and available to physicians automatically, i.e., on the CMS website, instead of requiring physicians to actively request that information piecemeal.

That way, physicians know precisely which drug source is used for any drug listed in a CAP category, in case they have preferences, such as for a given name brand of drug over its generic formulation. CMS' proposes that the onus should be on physicians to request NCDs under every conceivable HCPCS code within a given category "no later than the beginning of the election period. Considering the relative ease with which CMS can simply make this information that it already has available to the public or, at least, available to physicians, it should do so. Expecting physicians to add one more task to this election process is not only unduly burdensome, but creates another hurdle and disincentive to elect participation in CAP. In addition, requiring physicians to make inquiries will cause unnecessary delays in the process, along with extra costs in the form of administrative time and effort for both the physicians inquiring and for CMS to respond.

Recommendation- Drug Categories and Vendors' Disclosure of National Drug Codes (NCDs): Upon CMS's award of a vendor contract, CMS should publicly disclose the NDCs a vendor will provide, under the HCPCS codes in any CAP category. Physicians must be able to have this information available without requesting it from CMS and well in advance of the due date for CAP vendor election.

D. Physician Choice of Drug Categories and Vendor ("Claims Processing Overview")

Physicians will benefit from more flexibility, if they can select specific drug categories from more than one vendor's offerings, rather than being forced to purchase drugs from one vendor exclusively. This "cafeteria" concept will encourage more physicians to customize their vendor choices to their practice needs. Physicians can continue to use the ASP method for drugs that are either not included in CAP or are in CAP categories the physician does not select.[6]

With CMS' proposal, composite bids are constructed from bids on individual drug prices within a category, so vendors will have to calculate the profit margin spread within one category at a time.[7] This creates competitive bidding for contracts amongst vendors category to category, rather than comprehensive bidding across all categories. This will maximize the opportunity for each Part B drug category to stay at the lowest possible price. However, it may also motivate vendors to choose the least costly sources for any given drug to be offered under the general HCPCS Codes listed in any category. To the

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[6] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10755.

[7] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10762.

extent that the vendor's choice of drugs to offer does not meet the needs or preferences of physicians, there will be a disincentive to elect CAP. Especially for psychiatrists, it is essential that the psychotherapeutic category of drugs CAP offers includes a sufficiently comprehensive variety of drugs commonly used to treat their patients. Otherwise, there will be little incentive for psychiatrists to elect CAP, if it requires switching patient medications because it lacks a comprehensive drug category.

Recommendation- Physicians' Choice of Categories: APA urges CMS to allow physicians to select specific drug categories from more than one vendor. This will allow them more flexibility in obtaining drugs to meet their practice needs and an incentive to elect CAP. This will also create more bidding competition within each drug category, to maximize cost-savings for Part B drugs.

II. Vendor Bidding

A. "Competitive Acquisition Areas"

APA believes that competitive acquisition areas should be established based on single states, to allow for maximum competition in the bidding process. APA agrees with CMS that "this approach would also allow regional distributors to participate more easily in the CAP, thereby potentially increasing competition in the bidding process."[8] This way, even smaller distributors can bid and compete with larger entities and the advantages or disadvantages of a given market will be distributed across each state. Also, some physicians will have established business relationships with local vendors and will be able to continue those arrangements without disruption.

Regional areas can be defined to advantage certain distributors, whereas states automatically have fixed borders that cannot be manipulated. Even if this approach requires somewhat more effort on the part of large-scale bidders, it is those bidders who are best positioned to afford it. To the extent that this approach will maximize competition via a larger spectrum of bidding vendors, it has the potential to keep drug costs down for physicians and patients. It also will constrain monopolization of the market by large companies, who can bid low at the outset of the CAP process, in order to gain a large, initial market share and drive out smaller-scale competitors, then later raise prices because they have eliminated competitors. Keeping a state-centered approach may also make it easier for state-level licensing entities to oversee vendors' participation in the acquisition process and take local corrective measures, where necessary.

Recommendation- Competitive Acquisition Areas: Establish competitive acquisition areas based on single states, to maximize bidding competition and local oversight of vendors.

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[8] Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10753.

B. Vendors and Precluding Monopoly ("Regulatory Impact Analysis")

While CMS' proposed 42 C.F.R. Sec. 414.908(e) requires that there be a minimum of two vendors awarded contracts for a given drug category and area, the language of the proposed regulations does not prohibit subsidiaries from bidding against their parent companies or each other and both being awarded vendor contracts. Absent such a prohibition, large companies can essentially monopolize the bidding process by having multiple subsidiaries bid "against" each other and/or the parent company. In order to ensure true competitiveness in the vendor bidding process, APA maintains that it is essential for CMS to adopt regulatory language that specifically promotes adherence to antitrust principles and prohibits subsidiaries from bidding against and being awarded contracts with other subsidiaries of the same parent company or against the parent company itself. CMS should revise the language of Sec. 414.908(e) "*Multiple contracts for a category,*" Sec. 414.910(a) on the bidding process, and anywhere else necessary, to reflect this bidding restriction. If this is not done, the expectation will be that the cost-savings anticipated by this program are highly unlikely to come to fruition, due to the lack of true market competition among bidding vendors.

Recommendation- Drug Categories, Vendors and Precluding Monopoly: CMS should require full disclosure of a vendor's corporate relationships during the bidding process and take concrete steps to prevent monopolization by any one company within the bidding or contract award stages of the CAP program. This includes adopting regulatory language within Sec. 42 C.F.R. Part 414 that requires corporate-structure disclosure and specifically prohibits vendor subsidiaries from bidding against their parent company or other subsidiaries with the same parent company. CMS should revise the language of Sec. 414.908(e) "*Multiple contracts for a category,*" Sec. 414.910(a) on the bidding process, and elsewhere, to reflect this bidding and contract award restriction.

C. Vendors and Patient Privacy

CMS notes that CAP will require vendors to comply with all relevant federal and state laws. The physician's transmission of patient information to the vendor for prescription orders would need to be in a HIPAA-compliant format.[9] CMS views the vendor as a health care provider that would be a "covered entity" for HIPAA purposes, so that its standard HIPAA transactions, conducted electronically, would need to comply with HIPAA and the Privacy Rule.[10] However, once the vendors have this detailed prescription-related patient information, it is essential that CMS preclude them from using it in any other manner than that specifically required to fulfill the prescription order. While HIPAA does cover transmission of the patient's information from the physician to the vendor, once the vendor legitimately has the patient's information, it is

[9] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10756.

[10] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10761.

not prohibited by HIPAA from using this data for marketing purposes. While APA continues its endeavors to correct this HIPAA loophole through legislative means, APA urges CMS to confirm its commitment to respect for the privacy of patients by requiring the vendors to refrain from sharing, selling or otherwise using patient data for other than its original prescription-fulfillment purposes.

CMS should explicitly require that the vendors be prohibited from using this patient information in the following ways, which are examples and not all-inclusive: 1) direct marketing to the patients by mail, e-mail or telephone; and 2) sharing this database with or selling it to other corporate entities, including their own partners, affiliates, subsidiaries, sub-contractors, etc. Maintaining patient privacy with regard to psychotropic medications is a particularly important issue for psychiatric patients, since confidentiality is at the core of the psychiatrist-patient relationship. If patients do not trust that their medical information is private, they will be reluctant to seek or continue treatment, in many cases.

Recommendation- Vendors and Patient Privacy: CMS should explicitly prohibit vendors under CAP from using, sharing or selling patient information for any purpose other than that which is strictly related to fulfilling CAP orders.

III. Administrative Burdens upon Physicians ("Claims Processing Overview/ Statutory Requirements Concerning Claims Processing/Regulatory Impact Analysis")

CMS' proposed CAP system contains substantially burdensome administrative functions for physicians that may well outweigh the financial benefits of the program. They are ill-equipped to deal with the administrative burdens already imposed upon their practices and all of these cut into time with patients, cost staff time and add stress to the practice of medicine. In many cases, there are simple ways to streamline the system and eliminate the burdens upon physicians.

A. Extra Costs of Damaged and Returned Products

There are two unresolved issues under 42 C.F.R. Sec. 414 as to whom CMS expects to absorb certain costs within CAP. One concerns damaged goods, i.e., from "wastage, spillage or spoilage." The other is the shipping cost to return damaged drugs or unused drugs, where order fulfillment was in error, or where the drug was not administered when expected. CMS requires that vendors deliver the drugs directly to physicians' offices and that vendors' contract bids include "(a)ll costs related to the delivery," under Sec. 414.910(1).[11, 12] "Delivery" costs, presumably, include both

[11] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10754.

[12] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10771.

shipping and "handling" charges. Drug "wastage, spillage or spoilage" "may not be included" in bid prices, under Sec. 414.910(2).[13] The regulatory language is ambiguous, as "shall" is typically used to indicate a non-discretionary situation and "may" to indicate discretion. This could be interpreted as either prohibiting vendors from including "wastage, spillage or spoilage" in bid prices or as leaving it to the vendors' discretion, as to whether or not to do so. As a practical matter, it is not in the vendors' interest to include these projected losses in bids, since it would make a bid higher and CMS will choose among the five lowest, qualified bidders for contract awards.[14]

Vendors cannot recoup the cost of these losses through reimbursements, which are restricted to their bid drug prices and dependent upon administration of the drug.[15] Vendors will not wish to absorb the cost of damaged drugs or the cost of shipping returns. Are vendors expected to insure each shipment and include that insurance in the bid price as part of the cost of "delivery"? Will CMS allow the vendors to charge physicians for damaged drugs or returns? These questions are not yet answered, yet CMS needs to deal with them. The proposed regulations do not specifically prohibit vendors from charging physicians directly for such things, nor do they specify that vendors must absorb the financial loss, regardless of whether it is covered in the bid price. Physicians can only obtain reimbursement for administering a drug. So, losses from damaged or otherwise unusable drugs and the cost of returns fall between the cracks of the proposed system. By default, physicians who wish to return orders for any reason will be burdened with the mailing costs, unless CMS deals with this common occurrence in the proposed regulatory scheme.

There should be no potential for vendors to charge physicians for anything within the CAP program and physicians should not be burdened with the substantial cost of returning unused drugs. Physicians can only be reimbursed under CAP for drug-administration services, not for related drug charges. Apart from the physician's services, drug-administration services include bundled payment for clerical and inventory resources; other charges cannot be recouped. Physicians cannot be in the position of underwriting losses and returns attendant to handling CAP drugs, without experiencing a substantial financial disincentive for CAP election.

Recommendation- Extra Costs and Burden upon Physicians: CMS must adopt clear regulatory language to prevent vendors from charging physicians fees that physicians cannot recoup, such as for product returns or for damaged products. Physicians cannot be in the position of underwriting losses for damaged goods and return costs attendant to handling CAP drugs.

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[13] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10771.

[14] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10770.

[15] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10753.

B. Splitting Shipments and Tracking Numbers ("Claims Processing Overview")

APA agrees with CMS' proposal to allow physicians to order drugs from a vendor for a beneficiary's entire course of treatment at one time. However, APA remains highly concerned about the implications of CMS' proposal to allow a vendor to split the patient-specific prescription order into different shipments labeled with different prescription numbers, at the vendors' discretion.[16] How the additional prescription numbers would be generated and appear are not specified, i.e., whether they would reflect the original prescription number from the physician and have a shipment-specific suffix added, or whether they would be vendor-generated in some other manner.

CMS also does not specify how and when the vendor would convey the extra prescription numbers to the physician, who is then expected to keep a record of each separate shipment with each separate prescription number. This appears to cause two fundamental problems: 1) tracking of prescription numbers, where the original physician's prescription number for a patient order is added to by vendor-issued prescription numbers for split shipments to fulfill the same order; and 2) timeliness of drug availability for the patient.

There appear to be other potential points of confusion in the prescription number assignment process. CMS anticipates that the physician would use a prescription number when claiming reimbursement for administering the drug. However, if the vendor makes one shipment with the original physician-generated prescription number and the shipment contains ten doses of an injectable drug to be administered at different appointments, each physician claim would then have different dates but reference the same drug and same prescription number. This is likely to cause confusion at the claims-processing level, where the claims may be misconstrued as duplicate claims, resulting in delays or non-reimbursement. If the vendor splits shipment, it generates its own prescription numbers for the additional shipments. The physician then stores the drugs in those shipments for future use. Despite that they are the same drugs for the same patient, CMS expects the physician to use the shipment prescription number from the vendor, rather than the physician's original prescription number to track and make reimbursement claims. This excess of prescription numbers and multiple sources for their generation are, likewise, going to cause significant claims-processing confusion and reimbursement delays and denials to physicians.

APA strongly recommends that CMS adopt a simplified, streamlined tracking approach for shipments. Only the prescribing physician should be able to generate a prescription number. The vendor can assign split-shipment numbers that are tied to the original prescription number but vendors should not be self-generating additional prescription numbers for split shipments to fulfill one prescription order. Tracking confusion must be eliminated across all lines of the process. The physician can simply

[16] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10754.

enter the shipment number into the patient's prescription database upon receipt of the shipment, then use the prescription and shipment numbers for reimbursement claims.

Since the physician is obligated to use only one CAP vendor for a given drug category over the entire year of the physician's CAP election, the physician will be unduly dependent upon timely, correct shipments and ready access of drugs for patients' needs. If the shipments are not timely and/or accurate, then the physician is in a position of little recourse to ensure that a patient can get the right drug in time for a given appointment. Even an emergency order will not be very helpful in cases where a psychotic person requires an immediate injection of risperidone, for instance. Where psychotropic medications are to be administered during an appointment with a psychiatrist, if the drug is unavailable for the appointment, the patient's drug regimen will be severely disturbed and decompensation can occur quickly.

Recommendation- Split Shipments and Tracking Numbers: CMS should not allow vendors to split orders into shipments, unless they document to both CMS and the ordering physician that they have run out of inventory of a given product and that there is no recourse other than a split shipment.

APA strongly recommends that CMS adopt a simplified, streamlined tracking approach for prescription orders that vendors split for shipment. CMS should allow only the prescribing physician to generate a prescription number for a given order. The vendor can then assign numbers that are tied to but not equivalent to, additional prescription numbers. CMS should not allow vendors to generate their own prescription numbers for split shipments, as this will cause substantial confusion and delays in the claims process for physician reimbursement.

C. Emergency Drug Administration and Replacement

CMS proposes that, in emergency situations, a physician would treat the Medicare beneficiary from the physician's own medication inventories, then later be re-supplied under CAP. Of course, that assumes the existence of the necessary drugs in inventory, prior to the emergency. Precisely what CMS envisions as the source of such inventories is unclear, but the unstated assumption seems to be that these drugs were previously purchased with ASP reimbursement in mind. There is no provision under CAP for a physician to stock an inventory of drugs for emergencies, except by default, when drugs ordered for a specific patient are unused. Each prescription order under CAP is to be patient-specific; orders cannot be general for inventory stockpiling purposes.[17] After treating a patient with a drug in an emergency, the physician can re-supply the inventory with CAP-acquired drugs. But, CMS proposes that re-supply occurs only if the physician demonstrates the existence of all four conditions to the local carrier:

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[17] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10756.

> "We propose that in accordance with section 1847B(b)(5) of the Act, in emergency situations drugs acquired under the CAP could be used to resupply inventories of drugs administered by physicians. We propose that this process would apply if the physician could demonstrate all of the following to the local carrier: (1) The drugs were required immediately. (2) The physician could not have anticipated the need for the drugs. (3) The vendor could not have delivered the drugs in a timely manner. (4) The drugs were administered in an emergency situation."[18]

Since the physician could have acquired the same drug for the same patient through the usual CAP ordering process in a non-emergent situation, it is unclear why a physician must jump these four hurdles for that drug and patient in an emergent situation. There is no more cost to the public and no advantage to the physician, one way or the other. Whether the inventoried drug used for the emergency treatment was paid for initially by the physician or was CAP-acquired, the physician is simply replacing that which was legitimately used for patient treatment. There is no clear justification for treating a physician's reimbursement for drugs differently, based on whether the situation was emergent or not.

In addition, it is redundant and unduly burdensome to require the burden of proof to be on the physician to demonstrate the existence of these four conditions. The logic underlying imposition of these conditions is not clear. The scenario is that the physician has a drug in inventory that winds up being used in an emergency. By virtue of the physician determining that it is an emergency situation, conditions #1 and #2 are automatically met, as a matter of fact: *"(1) The drugs were required immediately;"* and *"(4) The drugs were administered in an emergency situation."* The point of requiring the physician to demonstrate that these factors exist, when the nature of the emergency inherently underscores their existence, requires elucidation. Condition #3 requires the physician to attest to that which is not even within his or her purview of knowledge; it is only within the vendor's: *"(3) The vendor could not have delivered the drugs in a timely manner."* It is not appropriate to require the physician to attest to facts which s/he cannot know. Clearly, the physician anticipated the future use of the drug in some way, since it was kept in inventory, so the physician cannot logically attest to condition *"(2) The physician could not have anticipated the need for the drugs."*

Imposition of these conditions is strictly within the discretion of the Secretary.[19] APA's position is that these should be eliminated altogether from the language of Sec. 414.906(e), as they appear to serve no genuine purpose.[20] Their only conceivable purpose is as a barrier to reimbursement that will allow claims processors considerable subjective leeway with which to deny physicians' claims. CMS already expects that the physician will note on the drug order that it is a replacement for an emergency

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[18] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10755.

[19] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10755.

[20] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10770.

administration of the drug. Therefore, at the point of vendor drug reimbursement, this will already be clear, as indicated on the claim form. In addition, if these conditions must be met as a prerequisite to physician reimbursement, there will be appeals of claims denials on this basis. That adds extra administrative costs to the claims process. In a cost-benefit analysis, these conditions add no real benefit and will be costly to administer, to physicians doing the extra documentation, to the claims processor and to those handling Part B appeals from claims denials for physicians.

If there is some need to track CAP drugs to differentiate emergency administration from the physician's-claim end, there is a simple method for this. By just checking a box captioned "Emergency Administration" on the claims form, the physician would be substantively and simultaneously addressing all of the concerns embodied within the four stated conditions, obviating any further need for proof. It must be left to the discretion of a physician, as to whether or not a patient is in an emergent situation and in need of drugs. The physician should not be penalized for that opinion with the threat of non-reimbursement. If physicians cannot be assured that they will be reimbursed for drugs administered in emergencies, this will be a substantial deterrent for many in electing CAP participation, especially for psychiatrists who frequently treat emergency patients.

In addition, eliminating these excessive steps will obviate the need for CMS' idea that a carrier should conduct post-payment reviews of emergency drug replacement claims, to determine whether physicians were in compliance with these requirements.[21] Alleviating the need for this layer of extra administrative time will result in cost-savings for the program.

Recommendation- Emergency Drug Administration and Replacement: CMS' proposed four conditions for physicians to prove that drugs were administered in an emergency should be eliminated. They are burdensome and serve no purpose, except as barriers to reimbursement. The physician can verify emergency administration of the drug by simply checking a box captioned "Emergency Administration" on the claims form. Alleviating the need for a carrier to conduct post-payment reviews of emergency drug replacement claims, to determine physicians' compliance, will result in cost-savings for the program.

D. "Furnish as Written" Orders and Medical Necessity

CMS proposes that, if the physician cannot obtain specific "formulations" or a product defined by its NDC number (indicating the manufacturer) under CAP, the physician can still use the ASP method to purchase those drugs, conditioned upon whether they are "medically necessary."[22] The physician would receive drug

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[21] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10756.

[22] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10755.

reimbursement under ASP and administration services reimbursement under CAP. The physician would specify on the order: "furnish as written." CMS does not define the term "medically necessary" either in the NFRP or in the proposed rules themselves. A lack of definition of this critical term makes it very difficult for physicians to comply with it for claims purposes. Whatever guidance about "medical necessity" CMS furnishes to carriers for claims processing should be afforded to physicians, so that they can more consistently fall within the expected parameters for CAP claims purposes. This guidance will serve as a first-line filtering mechanism for borderline cases, saving time and cost in claims processing. CMS' proposed approach does not anticipate allowing the physician's own determination of "medical necessity" to suffice. Instead, CMS defers to the physician's carrier to make its own, subjective determination on "medical necessity," and use this as a basis for denial of reimbursement.[23]

In addition, the actual proposed rule, Sec. 414.906(2)(ii) refers only to a "brand of drug" not a "formulation," as CMS indicates earlier in the NFRP. The drug brand and its formulation are not necessarily synonymous. For instance, the same manufacturer may use a brand name for a given drug, yet offer it in different formulations and with delivery systems.

Recommendation- Medical Necessity and CAP Exception: In order to clarify and correct both of these issues, APA strongly urges CMS to change the language of the proposed rule, Sec. 414.906(2)(ii), to read, as follows *(additional language in italics)*:

> "(ii) When medical necessity, *as determined by the treating physician,* requires a certain brand, *formulation (including but not limited to form, i.e., injection-administered), dosage strength, or delivery system* that the approved vendor, *elected by that physician,* has not been contracted to furnish under CAP."[24]

There is an additional benefit of clarifying this language and allowing the physician, who is best positioned to do so anyway, make the determination of "medical necessity." That is to alleviate the need for CMS' anticipated post-payment review by the physician's carrier of "furnish as written" orders, for the purpose of determining whether reimbursement was appropriate.[25] At the very least, the determination of "medical necessity" by the physician should be afforded the weight of a legal presumption, which would have to be rebutted by the local carrier, in accordance with specifically defined criteria, in order to deny a physician's claim on this basis. CMS should furnish guidance to physicians, as to what carriers consider to be acceptable

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[23] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10770.

[24] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10756.

[25] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10770.

factors for determining "medical necessity" so that physicians' orders can more consistently fall within the expected parameters for CAP claims purposes.

E. Unused Drugs

If a physician does not administer a drug to a beneficiary on the expected date of administration, CMS proposes to require physicians to do various tasks. These are, as follows: 1) notify the vendor when a drug is not administered, per Sec. 414.908(3)(vi); 2) reach an agreement with the vendor on how to handle the unused drug; and 3) generate a new order when the drug is to be administered to another patient, per Sec. 414.908(3)(iii), noting that the drug came from the physician's inventory, so that the vendor need not ship the drug.[26]

APA's position is that CMS does not need to require all these tasks from physicians. The first two are unnecessarily burdensome, time-consuming and add nothing of significant value to the tracking or claims process. These excessive administrative steps simply consume time for which the physician is uncompensated, and which could be better used in treating patients.

The only task that is *necessary* is No. 3. There does not seem to be a genuinely necessary purpose to the first two tasks. Each additional layer of tasks required of physicians in the CAP process creates a disincentive for participation. Therefore, this process should be as streamlined and efficient as possible, stripped of any steps that are of insignificant value. It is unclear why CMS believes so much consultation between the physician and vendor is necessary or desirable when a drug is not administered when expected. This will happen on many occasions, such as when a patient does not show up for an appointment, postpones an appointment, the drug delivery is untimely, or the physician is unexpectedly out of the office. CMS should delete this requirement, under Sec. 414.908(3)(vi), as it is unduly onerous to psychiatrists, especially those in community mental health clinics, who may have many patients who do not keep appointments for drug administration.

If the physician wishes to return the drug to the vendor, s/he can do so without prior consultation with the vendor. If the physician wishes to retain the drug in inventory, s/he should be able to do so without taking other steps. Once the physician accepts the drug delivery, the drug is under the physician's legal custody, unless it is returned to the vendor or administered to a patient. It is not as though there is a risk of diversion of the drug from its being untraceable. The vendor cannot receive reimbursement for the drug unless and until the physician's claim for reimbursement of its administration (to some patient) is approved. When the vendor's carrier matches prescription numbers from the vendor and physician during the claims process, this event triggers payment to the vendor.

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[26] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10770.

Recommendation- Unused Drugs: CMS should allow a physician the freedom to either return unused drugs to the vendor or retain the drug in inventory without taking other steps. The drug is under the physician's legal custody, unless it is returned to the vendor or administered to a patient. The vendor will be reimbursed for the drug when the vendor's carrier matches prescription numbers from the vendor and physician during the claims process. CMS should delete the requirement that a physician notify the vendor when a drug is not administered, under Sec. 414.908(3)(vi), as it is especially onerous to psychiatrists, especially those in community mental health clinics, who may have many patients who do not keep appointments for drug administration.

III. Vendors' "Dispute Resolution"

APA agrees that the CAP process should require that vendors receive a full drug reimbursement only after the physician's claim for reimbursement for administration of a drug has been approved. APA also agrees that vendors do not fall within the anticipated category of claimants who should use the Medicare Part B appeals process. Physicians and beneficiaries will continue to use the traditional Medicare Part B dispute resolution and administrative appeals process, under 42 C.F.R. 405.801, *et seq.,* for denials of CAP reimbursement claims.[27] Physicians should also be able to avail themselves of the federal administrative adjudicative process that is typically available to participants in federal healthcare programs, particularly as it concerns their compliance and sanctions for non-compliance, such as suspension, with federal programs.

CMS proposes that, instead, vendors use a process for dispute resolution through the vendor's designated carrier and reconsideration by CMS, as outlined in 42 C.F.R. Sec. 414.916.[28] The basic concept of using a dispute resolution process requires the existence of a dispute, which CMS' proposed process does not. It appears to merely be a vehicle with which vendors can pressure physicians, via the vendor's carrier, with the threat of recommending their suspension from the program. CMS' proposed process and rule strikes APA as highly flawed in both concept and execution. It inappropriately places the authority to make legal and quasi-legal conclusions about a physician's contractual and regulatory compliance in the hands of a biased, private insurance company allied with the vendor, who can also recommend to CMS that the physician be suspended from this federal CAP program. This dispute resolution process deprives physicians of proper due process through a neutral federal administrative adjudicative body and is also ultimately ineffective in meeting its stated goal.

Vendors should not be able to initiate a dispute resolution process in the manner CMS envisions. The underlying concept jumps from vendors not being paid on claims

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[27] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10757.

[28] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10771.

(at some unspecified order of magnitude) to an assumption that the physician is at fault by not filing a "clean claim," or administrative appeal, and therefore, should receive counseling by the vendor's carrier.[29] That is not dispute resolution, it is a unilateral, assumptive stance. Why counseling, if warranted at all, should issue from the vendor's carrier, rather than the physician's carrier is unexplained.

The baseline problem with this concept is that the vendor is able to determine, solely at its discretion, what constitutes a loss from its unreimbursed claims that "exceeds an acceptable threshold." This loss determination is what CMS envisions will trigger the vendor's ability to request that the vendor's carrier intervene with the physician, yet nowhere are there defined criteria for this threshold.[30] There is also no requirement to eliminate the real possibility that it is the vendor's own claims process that contains the flaws, which can be remedied at the vendor level. The proposed rule itself, Sec. 414.916, is even less precise, stating that the vendor may take such action when it is "not paid on claims submitted to the designated carrier."[31] This language requires no threshold, apart from it being more than one unpaid claim.

In addition, CMS does not define when a claim is "denied," for the purpose of triggering the proposed vendor's dispute resolution process, under Sec. 414.916(a).[32] Is it when the vendor's carrier cannot obtain a prescription number match for an approved physician's claim, so the vendor's carrier initially denies payment? Or, is it when the physician's claim has gone through the appeals process and has been denied at the highest level of administrative claims action? Since CMS' proposed system requires a physician to pursue administrative appeals on denied CAP claims, under Sec. 414.908(a)(3)(ix), it is logical that the end point of that administrative appeals process would constitute the time certain, at which a physician's claim could legitimately be considered "denied," as a final matter.[33] Since payment for the vendor's claim is conditional, as it depends upon approval of the physician's claim, the vendor's claim is, likewise, not truly denied until the physician exhausts all administrative remedies with respect to the claim. Only at that point of final denial on appeal, should the matter be considered "in dispute," and eligible for resolution through an alternative mechanism.

Given the detailed CAP claims databanks that will be available, there is no obvious reason why CMS cannot choose a defined percentage of claims denials from a

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[29] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10772.

[30] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10758.

[31] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10772.

[32] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10770.

[33] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10770.

given physician or group practice, which will automatically trigger a troubleshooting initiative. The first step should be that the vendor's designated carrier performs a root-cause analysis to find the reasons for the vendors' claims denials, which may reside with the vendor's own claims. If that proves not to be the issue, then it makes sense for the vendor's carrier to alert the physician's carrier about the problem and allow the physician's own carrier to investigate and intervene. Depending upon what the claims analysis reveals, interventions can be initiated to resolve specific problems at the vendor, physician or other claims systems points. If there turns out to be a dispute between the vendor's carrier and the physician's carrier as to where the claims problem lies, at that point there is a genuine dispute, for which a dispute resolution process would be appropriate.

APA does not agree with CMS' proposed rule, 42 C.F.R. Sec. 414.916. This rule would allow vendors to initiate pressure on the physician through the vendor's carrier, to "counsel" the physician as to his or her obligation "to file a clean claim and pursue an administrative appeal."[34] The vendor's carrier can recommend that CMS "review" the situation for the purpose of determining whether to recommend suspension of the physician's participation in CAP.[35]

Apart from the problem of an undefined trigger point that lies solely with the vendor, this approach to dispute resolution is ineffective, places too much power in the hands of vendors to pressure physicians and poses the vendor and physician into a polarized relationship. Insofar as it will not identify or solve problems well within the claims process, it contravenes its own purpose of getting vendors reimbursed and increases the likelihood that the same process errors or glitches will be repeated. Further, it places yet another burden upon physicians to handle administrative tasks that could be easily avoided. CMS' approach glosses over the systems trouble-shooting step entirely. CMS places the burden squarely at the feet of physicians to respond to pressure from vendors and the physician's carrier, even when reasons for the vendors' non-reimbursements have not yet been ascertained and may lie with them in the first place.

If the goal is to increase the number of vendor claims that are reimbursed, the first step is to identify where in the claims process the barrier to reimbursement lies, then remedy it. This process should be left initially to the vendors' and physicians' carriers to sort out. Each carrier can provide notification as to the denial of the vendor's claim and reason. If the reason appears to be at the physician's carrier end, i.e., a wrong prescription number or missing information, it can be resolved there. This could also be true for the vendor's carrier. Errors will occur at any number of steps in a claims process and the first-line approach should be for carriers to resolve the problems directly with

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[34] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10772.

[35] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10758.

their claimants. The second step is for the vendor-claimant to use the appeals process, where applicable.

The other problematic aspect of CMS' proposed "dispute resolution" process is that it embues adjudicatory authority with a private, biased insurance carrier that has a legal fiduciary duty to protect the interests of the vendor. This is contrary to our established principles of jurisprudence, where adjudication is expected to be by a neutral party. If a judge had similar connections to a case she were adjudicating, she would have to recuse herself on the basis of conflict of interest.

This private insurance company not only has the power, at the vendor's behest, to investigate the physician's "performance" (a term undefined by CMS), it investigates, "recommends" to CMS whether the participating CAP physician has been "meeting the claims and appeals obligations," and has been filing CAP claims "in accordance with the requirements for physician participation in the CAP as set forth in Sec. 414.908(a)(3), gathers information from the physician's carrier, and recommends whether the physician should be suspended from CAP.[36] Determinations as to the physician's compliance with federal regulations and the CAP contractual agreement are legal determinations. Apart from problems that the biased vendor's carrier is making these determinations, there is no requirement as to the qualifications or training of the person(s) making these investigations and legal determinations. To the extent that any exists at all, due process is absolutely minimal for the physician throughout this process. The physician has no articulated right to obtain or provide information during this process.

The hearing officer does not have authority to compel compliance with a subpoena, so that the physician could force either the vendor or the carrier to produce witnesses, papers or other evidence.[37] The record is unilaterally developed by the vendor's carrier. Physicians should be able to obtain all documentation that forms a basis for any of these administrative actions and this right should be articulated specifically within the regulations. CMS reviews only the suspension recommendation by the vendor's carrier but there is no requirement that CMS obtain more information or even that it review the carrier's underlying documentation.[38]

If CMS suspends the physician from CAP, the physician can request a reconsideration of the decision. Reconsideration must be filed "within 30 days of receipt of CMS decision letter." However, CMS does not specify how the receipt date is to be determined, even though this is a crucial cut-off point for reconsideration. This should be clearly specified. A hearing will not be provided at the physician's request or at all, as a

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[36] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10772.

[37] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10772.

[38] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10772.

matter of course. Only informal hearings may be provided and then, only at the discretion of the hearing officer. There are also no stated required qualifications for the hearing officer who can, apparently be anyone whom the director of the CMS Center for Medicare Management or its designee appoints. Even if an informal hearing is granted, that hearing officer's decision is final, "unless the director of the CMS Center for Medicare Management or its designee chooses to review that decision within 30 days."[39]

To summarize, a physician can be suspended from CAP, based on a unilaterally created record and recommendation made by non-attorneys in a biased, private company: the vendor's carrier. The only articulated requirement for CMS is that it review the carrier's suspension recommendation, but not the underlying record. If CMS goes along with the recommendation and suspends the physician from CAP, it is then that the physician can request reconsideration and submit evidence on his or her behalf. The physician cannot request a hearing. If an informal hearing is held, the physician cannot have subpoenas for evidence or witnesses enforced. The hearing officer's decision is final and CMS does not have to review it. If CMS does review it, the final determination is published in the Federal Register. It is highly unlikely that the physician can pursue other legal avenues of relief, unless and until s/he has exhausted all administrative remedies, which is typically a court's prerequisite to exercise jurisdiction over such a lawsuit.

The physician can, therefore, go through the entire investigatory, suspension and reconsideration process conducted by an interested, private company, without having any attorneys or other legally trained persons involved, and without even an informal hearing to present evidence, be represented by an attorney, or to call witnesses. It is unclear how much, if any, information from either carrier or from the vendor the physician can obtain. This process, as envisioned by CMS, does not incorporate a level of legal standards, including due process, that should be expected with regard to a physician's participation in and suspension from a federal program. Depriving a physician from a neutral, proper adjudication, hearing and appeals process under CAP is reprehensible and will certainly create a strong disincentive for physician participation.

APA is even more concerned about CMS' proposal to publish final reconsideration determinations in the Federal Register that will announce to the public any physician's suspension from the CAP program. For physicians in group practices, their reputations can be inalterably ruined by inclusion in the suspension determination for the group, even if they themselves are completely innocent. This will undoubtedly result in a number of libel lawsuits filed by physicians against CMS, particularly in light of the questionable basis for suspensions under this proposed "dispute resolution" process.

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[39] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10772.

An informal hearing is possible but it is discretionary and the hearing officer is appointed the CMS.[40] Again, there are no specified qualifications for the hearing officer. Basically, no one in this process even has to be an attorney, despite that the result of the process can be the physician's suspension from a federal program. This action, especially when made a matter of public record in the Federal Register, can also follow a physician and create adverse consequences for future participation in federal programs.

The vendor's designated carrier makes investigations and provides legal and quasi-legal determinations to CMS, as to the physician's adherence to contractual obligations under CAP. This is highly inappropriate for several reasons. An administrative process to determine a physician's compliance with legal obligations under CAP and to generate evidence upon which an administrative decision will be made should be unbiased and conducted by a federal administrative body from the start. To have the vendor's claims carrier conduct these tasks is out of line with judicial principles. After all, a serious business interest is at issue here and can be revoked, that is, any benefits of participation in the CAP program. In addition, a record of non-adherence to the legal requirements of participation in a federal program may haunt a physician's record for many years and impede the ability to participate in that or other programs in the future.

The vendor's carrier is not an unbiased, disinterested party; its interest is in obtaining money for the vendor by ensuring that the physician's claim is approved. The vendor's carrier is also not a formal administrative adjudicatory body, yet the proposed rule embodies it with the responsibility to actively investigate the physician and to make recommendations to CMS as to the physician's legal adherence to the CAP program's requirements. CMS is not even *required* to gather additional evidence itself after the vendor is done, and prior to determining whether or not to suspend the physician from CAP. CMS only anticipates doing so "if necessary," though that is also undefined.[41]

As with other administrative adjudications related to federal programs, it is CMS' obligation to have first-line investigations, legal compliance determinations and recommendations for action based on these to be performed by neutral parties that are not involved in financial dealings of the CAP program. If CMS is unable or unwilling to take on this task, then it could either be outsourced to a governmental or different private entity. The vendor's carrier is a wholly inappropriate choice for that role. Physicians should not be placed into the position of having their rights under a federal program seriously compromised by the actions of a reimbursement claims carrier, rather than having the benefit of adjudication by a proper federal administrative adjudicatory body.

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[40] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10772.

[41] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10757.

Recommendation- Vendor Dispute Resolution: CMS should substantially revise the dispute resolution process and its attendant regulatory language, to create a neutral, federal administrative adjudicatory and appeals process that includes due process for the physician. When specific criteria are met, which CMS should clearly define, the process should allow the physician's carrier to investigate the physician's compliance with CAP, rather than allowing the vendor's carrier to have this role. CMS should objectively define in 42 C.F.R. Sec. 414.916 a threshold percentage of claims denials from a given physician or group practice that can trigger this inquiry and implement a systematic, troubleshooting approach to determine the reason for a vendor's claims denials. CMS should also define a "denial" of a claim, for dispute resolution purposes, as a final denial on appeal, after the physician has exhausted administrative remedies. Neither the vendor nor its carrier should be allowed to make legal or quasi-legal determinations as to a physician's compliance with CAP obligations, nor should either be allowed to request or recommend that a physician be suspended from CAP, as CMS proposes. Requirements for the training and qualifications of hearing officers and others involved in the final levels of this process should be articulated. Physicians should be able to request a hearing and to obtain all documentation that forms a basis for any of these administrative actions; these rights should be articulated specifically within the regulations.

V. Additional Concerns

APA remains concerned about the interplay among CMS' proposed CAP system, its recently proposed electronic prescribing standards (about which APA filed comments on April 5, 2005) and Medicare Part D coverage of drugs. The intersections of CAP with these other elements are not described in the CAP NFRP, but require elucidation by CMS. For instance, physicians who elect CAP must transmit substantial amounts of patient information to vendors, in the course of making prescription orders. While CMS does note that the order transmitted "may occur in a variety of HIPAA-compliant formats, such as by telephone with a follow-up written order," an example falling outside of e-prescribing parameters, CMS does not discuss how e-prescribing requirements fit into CAP orders or other electronic information transmissions.

CMS discusses using PIN and UPIN identifiers for CAP orders, but emphasized wanting to use a different system of National Provider Identifiers (NPIs) for e-prescribing, as of January 1, 2006. The identification number issue needs to be sorted out. CMS must choose a consistent number across all programs that is traceable to a specific physician's prescribing activities, for many reasons, including protecting physicians against unwarranted fraud and abuse allegations, where prescriptions and claims are generated under their identification number but without their knowledge.

Similarly, physicians should not have to be included in a group-practice election, if they do not wish to elect CAP as individuals. CAP election should be strictly on an individual basis, to keep prescriptions traceable to specific physicians, thereby protecting them against inclusion in fraud and abuse investigations undertaken against a

Recommendation- Split Shipments and Tracking Numbers: CMS should not allow vendors to split orders into shipments, unless they document to both CMS and the ordering physician that they have run out of inventory of a given product and that there is no recourse other than a split shipment.

APA highly recommends that CMS adopt a simplified, streamlined tracking approach for prescription orders that vendors split for shipment. CMS should allow only the prescribing physician to generate a prescription number for a given order. The vendor can then assign numbers that are tied to but not equivalent to, additional prescription numbers. CMS should not allow vendors to generate their own prescription numbers for split shipments, as this will cause substantial confusion and delays in the claims process for physician reimbursement.

Recommendation- Emergency Drug Administration and Replacement: CMS' proposed four conditions for physicians to prove that drugs were administered in an emergency should be eliminated. They are burdensome and serve no purpose, except as barriers to reimbursement. The physician can verify emergency administration of the drug by simply checking a box captioned "Emergency Administration" on the claims form. Alleviating the need for a carrier to conduct post-payment reviews of emergency drug replacement claims, to determine physicians' compliance, will result in cost-savings for the program.

Recommendation- Medical Necessity and CAP Exception: APA strongly urges CMS to change the language of the proposed rule for CAP exceptions, Sec. 414.906(2)(ii), to read, as follows *(additional language in italics)*:

> "(ii) When medical necessity, *as determined by the treating physician*, requires a certain brand, *formulation (including but not limited to form, i.e., orally, injection-administered), dosage strength, or delivery system)* that the approved vendor, *elected by that physician*, has not been contracted to furnish under CAP."[42]

Alternatively, the physician's determination of "medical necessity" should be afforded the weight of a legal presumption, which would have to be rebutted by the local carrier to deny a physician's claim. CMS should furnish guidance to physicians, as to what carriers consider to be acceptable factors for determining "medical necessity" so that physicians' orders can more consistently fall within the expected parameters for CAP claims purposes.

Recommendation- Unused Drugs: CMS should allow a physician the freedom to either return unused drugs to the vendor or retain the drug in inventory without taking other steps. The drug is under the physician's legal custody, unless it is returned to the vendor or administered to a patient. The vendor will be reimbursed for the drug when the vendor's carrier matches prescription numbers from the vendor and physician during the

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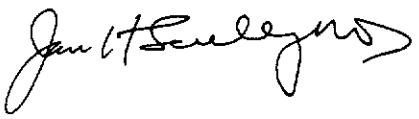
[42] CMS Proposed Rule: "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B;" CMS-1325-P [Federal Register: March 4, 2005 (Volume 70, No. 42)]; at 10770.

claims process. CMS should delete the requirement that a physician notify the vendor when a drug is not administered, under Sec. 414.908(3)(vi), as it is especially onerous to psychiatrists, especially those in community mental health clinics, who may have many patients who do not keep appointments for drug administration.

Recommendation- Vendor Dispute Resolution: CMS should substantially revise the dispute resolution process and its attendant regulatory language, to create a neutral, federal administrative adjudicatory and appeals process that includes due process for the physician. When specific criteria are met, which CMS should clearly define, the process should allow the physician's carrier to investigate the physician's compliance with CAP, rather than allowing the vendor's carrier to have this role. CMS should objectively define in 42 C.F.R. Sec. 414.916 a threshold percentage of claims denials from a given physician or group practice that can trigger this inquiry and implement a systematic, troubleshooting approach to determine the reason for a vendor's claims denials. CMS should also define a "denial" of a claim, for dispute resolution purposes, as a final denial on appeal, after the physician has exhausted administrative remedies. Neither the vendor nor its carrier should be allowed to make legal or quasi-legal determinations as to a physician's compliance with CAP obligations, nor should either be allowed to request or recommend that a physician be suspended from CAP, as CMS proposes. Requirements for the training and qualifications of hearing officers and others involved in the final levels of this process should be articulated. Physicians should be able to request a hearing and to obtain all documentation that forms a basis for any of these administrative actions; these rights should be articulated specifically within the regulations.

Thank you for your consideration of these comments.



James H. Scully Jr., M.D.
Medical Director, American Psychiatric Association

Submitter : Mrs. Dawn Holcombe **Date:** 04/26/2005

Organization : Oncology Network of CT LLC

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Please see the attachment to this form regarding my serious concerns about the viability of the CAP program as proposed and its insuitability for oncology care.

CMS-1325-P-428-Attach-1.DOC

Delivered in an email attachment through the online comment process

April 26, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS –1325-P
P.O. Box 8010, Baltimore, MD 21244-8010.

RE: CMS – 1325-P, Comments on the Notice of Proposed Rulemaking for the Competitive Acquisition of Outpatient Drugs and Biologicals under Part B

Dear CMS:

The Oncology Network of Connecticut, LLC (ONC) welcomes the opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) on the proposed rules implementing provisions of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) requiring establishment of a competitive acquisition program (CAP) for certain Medicare Part B drugs.

On March 4, 2005, the Centers for Medicare and Medicaid Services (CMS) published a proposed rule implementing the Competitive Acquisition Program (CAP) for Medicare Part B drugs. The CAP program was established by Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) and is intended to provide physicians with an alternative way of obtaining Medicare Part B drugs. Under CAP, beginning January 1, 2006, physicians who choose to participate in CAP will obtain Medicare part B drugs from vendors who have been selected through a competitive bidding process. Under CAP, vendors, not physicians, are responsible for billing Medicare carriers and collecting beneficiary co-payments.

Upon review of the proposed rule by members of community oncology practices, the group that is supposed to be served by the CAP program as a viable alternative to the ASP + 6% program, we have identified a number of serious concerns regarding CMS' approach and the program's proposed structure and operations that render the program unworkable for oncologists.

I. Categories of Drugs to be included under the CAP.")

CMS proposes three phase-in options:

Option 1 – Under Option 1, CMS would initially implement the CAP for a limited set of drugs that are typically administered by oncologists. Drugs typically administered by other specialties would be included over the next few years. .

Option 2 – Under Option 2, CMS would choose a limited set of drugs that are typically administered by one or more physician specialties that use Part B-drugs less intensively.

Option 3 – Under Option 3, CAP would be implemented for all Part B drugs that are furnished incident to a physician's service regardless of specialty.

Comment: These options are less a request for comment than a request for preferred choices. One would expect that once CMS determines a final option, adequate opportunity for public comment will be given before enforcing one of the options on physicians. Regarding our preferred choice: Oncology is a complex specialty and starting a program that disrupts the normal flow of business and clinical operations as dramatically as this proposed rule does without first investigating the impact could be disastrous to access for cancer care for Medicare patients. Please do not institute a CAP program as outlined in this proposal for oncology services unless all the issues and concerns raised by practicing community oncologists are given fair review. In the proposed rule itself, CMS states that the Secretary has authority to exclude drugs and biologicals from the CAP on the grounds that including those drugs would have an adverse impact on access to those drugs and biologicals. As you will see from comments throughout the rest of this letter, for the Secretary NOT to exclude oncology drugs on that basis would be directly in opposition to the reason for creating such authority.

Because, as will be explained further in these comments, the CAP program itself provides no recognition of the very real operating costs and burdens placed upon physician practices by implementation of this program, the resulting adverse impact that the program itself will place on physician practices should, once studied, serve to exclude oncology drugs from the CAP program under the above mentioned Section of the act. CMS should take the time to quantify that adverse impact before implementing the CAP program.

1. Statutory Requirements Concerning Claims Processing

Under this section of the proposed rule, CMS sets forth criteria for resupplying inventories of drugs administered by physicians.

Comment: The rules under which CAP drugs may be used to resupply inventories of physicians do not address certain common reasons why a CAP drug may not have been used. About one-third of the time, a scheduled treatment for an oncology patient does not happen as planned. If patient needs changed and an alternative regimen is indicated, that may not be an "emergency", but it is highly unreasonable to expect a patient to arrive, be tested, require the physician to submit another order, and tell the patient to return in another day or two when the new mixture of drug arrives (hoping that patient status has not changed again in the interim.)

How would the CAP program address restocking of drug if the physician uses a drug from his private inventory in a category covered by the CAP vendor, but the CAP vendor doesn't carry that particular drug? The physician has the right to expect accurate replacement, without substitution.

Under the proposed rule, 42 C.F.R. 414.908, physicians will be given the opportunity to select an approved CAP vendor on an annual basis. Physicians must complete and sign a CAP election agreement. In addition, the physician will be required to submit a written order or prescription to the approved vendor, provide information to the approved vendor to facilitate collection of applicable deductibles and coinsurance, notify the vendor when a drug is not administered, agree to file a "clean" Medicare claim within 14 days of the date of drug administration, and agree to submit an appeal accompanied by all required documentation necessary to support payment if the participating CAP physician's drug administration claim is denied. Physicians will also have to maintain a separate electronic or paper inventory for each CAP drug obtained.

No provision is made to compensate the physician for any of the above activities. Yet, if a vendor is not paid on claims, the vendor may appeal to the designated carrier to counsel the responsible participating CAP physician and if the problem persists, the vendor may ask the carrier to investigate the physician's performance and recommend the suspension of the physician's CAP election agreement. While the proposed rule does provide for reconsideration and appeal of a physician's exclusion, if the carrier's decision is ultimately upheld, "CMS publishes a final reconsideration determination against the participating CAP physician in the Federal Register." Proposed 42 C.F.R. § 414.916(b).

This section of the proposed rule also sets forth a mechanism for physicians to order drugs and for vendors to ship drugs to physicians and then receive payment from the carrier.

Comment: CMS states "It is not our intention to restrict the physician's flexibility when ordering drugs from a CAP vendor, or to require that a physician participating in CAP would order drugs differently from a CAP vendor than he or she would a non-CAP vendor." By definition, the CAP process creates a dramatic and operationally significant change in ordering procedure. Physicians order from non-CAP vendors to stock a single, centralized, inventory. There is no need for staff or systems to track beyond basic drug quantity levels. CAP imposes a requirement for staff and systems to track inventory on a per patient, and even per prescription basis. Additionally, CAP creates a mandatory vendor imposition on the physician which will probably not be the physician's vendor of choice, thus creating double effort to place and track orders and shipments and product. CAP formularies will narrow a physician's choices for product within a category and create extra work for the office if the products provided by a CAP vendor are deemed to be unsuitable from the physicians' quality and operational perspective, since alternative product will need to be ordered.

Physician practices do not now provide to external parties, outside of the carrier claims, additional information such as that expected under the CAP program to be provided to CAP vendors. This is a completely incremental burden on staff and system resources, totally uncompensated under this proposal. The expectation that a physician would send a CAP vendor one prescription for an entire course of treatment but that a CAP vendor

would create a separate prescription number for each shipment component of that course of treatment, and that the physician practice would be required to track each prescription number for submission on the claim form creates an operational nightmare for practices. When the reality is that 1/3 of the time planned courses of treatment change, this creates great potential for confusion and error on the part of all involved.

The proposal states that "the drug and prescription number would be shipped to the physician and would be maintained until the date of drug administration." There is no recognition of the significant drug handling and inventory costs of that expectation. MedPac staff recently studied the costs of such drug handling and inventory in the hospital outpatient setting and identified that 26% to 28% of drug costs were incurred in such handling. (See MedPac meeting testimony – in the transcripts from the meeting held March 10, 2005). Oncology practices have long maintained that such costs in their offices run about 12% of total drug purchase expenditures. With recompense for these costs under the CAP program, physicians will find little incentive to consider using the program. These costs are not now recognized in any other CMS payment to oncologists.

The required prescription numbers are not part of the National Data Set created under HIPAA in recent years, and would be a burden to oncology practices to address in their current practice management systems, as well as a significant cost item.

CMS is seeking public comment on whether physicians must obtain all categories of drugs from a particular CAP vendor, or whether physcians should be allowed to choose the categories they wish to obtain. Absolutely, physicians must be given a choice of categories. As mentioned previously, CAP vendors may create formularies that are inconsistent with the physician's preferred medical practice, or may ignore certain variations in drug approvals or indications within categories. Oncology care is so complex that without the flexibility to deselect certain categories, quality and patient access risks increase dramatically.

The data that the physician is required to transmit is far greater than that used in writing a prescription. The CAP program is inserting a full layer of complexity and data transfer that now does not exist and will create increased administrative cost at all levels for very little additional value. Physicians do not have the staff or the resources in current practice structure to comply with these rules, however, if staff must be added to comply, there is no planned compensation to cover the costs of compliance.

Comment: If physicians choose to place "furnish as written" modifiers on their drug orders, they are still subject to post payment reviews and carrier determination that a specific NDC number was not medically necessary will result in a claim denial. That process takes the medical decisionmaking completely out of the physician hands, yet it is the physician who holds the responsibility and liability for the quality and effectiveness of drugs used for patient care, and who has access to the full information about the patient's condition and health status.

The CMS proposal states that "the physician would notify the vendor and reach an agreement on how to handle the unused drug consistent with applicable State and Federal law." should a drug ordered not be administered. This CAP proposal ignores the fact that most pharmacy regulations indicate that drug, once ordered in a patient's name, may not be returned or reused or reshelved. The entire process of converting oncology inventories from a single centralized non-patient specific inventory to individualized patient inventory will bring millions of dollars of incremental waste into the medical system, on a per practice basis – waste that does not now exist under the current general inventory system.

2. Vendor Quality Control

The proposed rule provides that quality and service issues that relate to the vendor's performance are treated through the vendors own, internal grievance process.

Vendors are being paid to delivery highly volatile and at times, toxic drugs to physicians who need them to treat critically ill patients. It is essential that vendors are held to the highest standard for quality and performance. Doctors, who will be dependent on the vendors to obtain these drugs, need to know that when complaints are raised about poor quality and performance, carriers and CMS will take them seriously. Vendors who fail to perform should be subject to investigation and sanction, up to and including exclusion from the program. It is unrealistic to believe that doctors will participate in CAP if there is no effective process for addressing quality concerns and if they believe they have no recourse if a vendor is not performing as expected. The program should also make vendors responsible for liability related to any omissions or errors in handling these drugs within their quality parameters, and for failing to ensure that purchased drug cannot be pedigreed back to the manufacturer.

3. Dispute Resolution

Pursuant to proposed 42 C.F.R. § 414.908, physicians will be asked to make an election and select a qualified CAP vendor on an annual basis. Once selected, the physician will only be able to go to another vendor if the approved vendor ceases to participate in CAP, or other exigent circumstances defined by the Secretary such as when the CAP physician relocates to another competitive acquisition area or leaves a group practice that is participating in CAP.

Comment: While the statute does provide for an annual election, nothing in the statute requires or supports the use of a "lock-in" period for physicians. CMS must be mindful that vendors would be inclined to charge higher rates to their captive customers if a lock-in period is required, while physicians are unlikely to sign up for the program if they cannot leave it at will. This is a new, untested program. If physicians develop serious concerns about the vendor, or the program, or unanticipated costs of supporting the program, as small businesses with a low capacity for financial risk, they need the flexibility to depart.

4. Contracting Process – Quality and Product Integrity Aspects

While vendors will be required to bid on all HCPCS codes within a category, (e.g. drugs used by oncologists), CMS is proposing that vendors not be required to provide every National Drug Code associated with a HCPCS code. In effect, this gives a vendor permission to establish a formulary by choosing which drugs it will make available through the CAP.

Comment: When a health insurer or prescription drug plan limits access to drugs through a formulary, certain safeguards generally are required to ensure that patients are assured access to medically necessary drugs and that formularies are not overly restrictive or driven solely by pricing. For example, under Medicare Part D, formularies must be developed by Pharmacy and Therapeutics (P&T) committees program. Formularies must also be non-discriminatory and must provide for exceptions and appeals. Finally, prescription drug plan sponsors are prohibited from making certain formulary changes and if formulary changes are made, plans must provide notice or a one time supply to assist the beneficiary through transitions.

Unlike Medicare Part D, however, CMS has not proposed any minimum standards or safeguards to govern which drugs must be covered by CAP vendors within a designated category of drugs. If vendors are allowed to restrict access, or if they are allowed to change the drugs offered without notice to the participating physicians, physicians are unlikely to elect to participate in CAP. For those that do elect to participate, the absence of safeguards is troubling, especially given the absence of clear standards allowing physicians to disenroll from CAP based upon vendor performance. (See comments below regarding CAP Program Operations.)

Oncology care is complex to administer, and while active ingredients may be similar, inactive ingredients of drugs within a category may act in quite different fashions when combined with the rest of the drugs in a complex multi-treatment regimen. CMS states that "we are proposing that vendors will not be required to provide every National Drug Code associated with a HCPCS code." Physicians must be provided with full disclosure prior to selecting a CAP vendor of each brand of drug that vendor will carry, and given the option to not receive certain categories of drugs from a CAP vendor. Without that opt out protection, the operating and quality of care costs of allowing vendors to restrict their inventory to what becomes the cheapest drug for them to provide will be significant because physicians will be facing inventories full of the drugs they have always avoided (the version of a drug that takes extra time to reconstitute – or one that fails to mix properly, leaving particulate matter and needed benefit at the bottom of the bag instead of in the patient). Formularies created for the purpose of saving the vendor acquisition costs may become so limited that physicians will be forced to practice using "dispense as written" specificity for drugs and work outside of the CAP program through the ASP program, incurring cost and additional effort on all sides.

Some categories of drugs may include drugs that have differing FDA approvals or indications. A prime example are the Procrit and Aranesp drugs. These are commonly considered interchangeable, but in fact do have differing indications. There are also two interferon drugs on the market, but each have different indications and approvals. A vendor may bid for one drug in the category and create a formulary based upon market share manufacturer pricing, and thus not make the other drug available in that category. However, if physicians who elect the CAP program are required to acquire drugs in a certain category only from the CAP vendor, they are left unable to acquire the other drug even if it were the only one in that category with a given indication. Indications change frequently, and the bidding process for CAP vendors doesn't seem to leave room for changing category contents as indications change. The variable nature of oncology care and rapidly changing approvals and indications for different drugs and combinations of drugs make formulary management of oncology cumbersome and ineffective.

5. Collecting beneficiary co-payments

The statute requires that the vendor bill Medicare and the beneficiary, and that the beneficiary may not be billed until after the drug has been administered to the beneficiary. CMS is proposing that the vendor be allowed to bill the beneficiary and/or his or her third party insurance after drug administration has been verified by matching the physician claim with the vendor claim using the prescription number, and final payment is made by the Medicare program.

Comment: Despite the impact on cash flow, physicians generally are reluctant to refuse to treat a patient who cannot afford to pay a co-payment. Vendors, however, are not ethically or legally responsible for the course of a patient's treatment. If a vendor is unable to collect co-payments from a patient, nothing prohibits the vendor from stopping delivery of drugs to the physician's office. Allowing vendors to stop delivering drugs to an outpatient setting is likely to endanger patients or force them into more costly in-patient settings for treatment. Further, physicians could be exposed to liability if the physician is unable to complete a course of treatment because a vendor is refusing delivery. Under the circumstances, physicians must be permitted to obtain drugs through the ASP system.

6.. Timeframes for routine and emergency shipment

CMS is seeking comments on how to define timely delivery for routine and emergency drug shipments. CMS is proposing that routine shipments of drugs furnished under CAP would occur within one or two business days. However the duration of the delivery time period must not exceed the drugs stability in appropriate shipping containers and packaging. CMS also proposes that emergency drug orders be furnished on the next day for orders received by the vendor before 3 p.m. (vendor's local time). CMS is seeking comments on the feasibility of providing same-day deliveries received for emergency situations.

Comment: Same day deliveries are feasible and vendors should be required to meet this standard when drugs are needed on an emergency basis. At the time the drug is ordered, the physician should receive a commitment from the CAP vendor for a day and time of delivery, and vendors must be held accountable for compliance to that commitment.

7. Bidding Entity Qualifications

Vendors are expected to show a history of delivering Part B injectable drugs for at least 3 years. Oncology drugs are complex, with strict parameters for handling and storage. CAP vendors should be expected to show a history of at least 3 years of delivering each category of drugs for which they submit a bid. Experience with other drugs does not guarantee successful experience with oncology drugs, and the risks and liability for Medicare patients and physicians is too great to allow neophytes the responsibility of handling oncology and supportive care drugs.

8. Conflicts of Interest

The CMS proposal sets forth a code of conduct for CAP vendors, and identifies a conflict of interest as being "where a drug vendor, its representative, or contractor provides a product or service for a Medicare provider or beneficiary and the drug vendor, representative or contractor has a relationship with another person, entity product or service that impairs or appears to impair the drug vendor's or contractor's objectivity to provide the Medicare covered product or service." However, the creation of formularies for the purpose of steering market share toward one drug in a category over another in response to contracting discounts and rebates would appear to meet this definition of conflict of interest. If physicians are required to acquire drugs within categories as defined and by the CAP vendor, and the CAP vendor offers only a limited selection of the possible drugs, the CAP vendor has restricted the market of available drugs to their financial gain, and to the detriment of access to care for Medicare beneficiaries and their physicians.

9. CAP Bidding Process – Evaluation and Selection

The bidding process specifically excludes recognition of any costs related to the administration of the drug or wastage, spillage, or spoilage in submitted bids. Wastage,

spillage and spoilage are part of the cost of doing business with fragile and delicate stability products. It is unreasonable to exclude these costs of drug handling from both the vendors that ship drugs and the physicians who process and administer the drugs.

The composite bidding process ignores the quality issues of specific drugs in any given category. Drugs are automatically eliminated from bidding consideration if not obtainable at significant enough savings to the Medicare program, yet the cheapest and possibly least usable versions in a category may be the only drugs being made available through the CAP vendors.

10. Beneficiary Education

There is a real, but unrecognized additional cost pending for Medicare beneficiaries if the responsibility for copayment collection moves from the physician practice to the CAP vendor. CAP co-payment collection policies may lead to denials and reduced access to care for some Medicare cancer patients. CMS is not proposing to require physicians to provide beneficiaries with education on the program, there will be a significant administrative burden for physician practices caused by the program. Patients rely on their physicians to guide them through the treatment process, and any disruption of care will send patients immediately back to the physician office with a variety of physicial, financial, medical and psychosocial issues.

11. Physician application process

CMS is estimating that physicians will need 15 minutes each to fulfill the application requirements. The decision process will actually be far more complicated. As stated elsewhere in the CMS proposed rule, practices will need to evaluate the costs of purchasing and acquiring drugs under the ASP option, and compare the costs of acquiring drugs under the CAP program, plus evaluate discrepancies between the drugs now selected for patient care and whatever specific drugs are carried under the CAP vendor formulary – and assess any relevant issues for patient care and operational burdens. The CMS proposed rule assumes that physicians must maintain a separate electronic or paper inventory for CAP drugs, but reality dictates that a physically separate inventory will also be needed, with all the attendant costs.

12. Regulatory Impact Analysis

For purposes of the RFA, physicians and non-physician practitioners are considered small businesses if they generate revenues of $8.5 million or less. This rule dramatically underestimates the impact on physician practices, even practices participating in the CAP program, due to underestimation of costs of unreimbursed drug handling and inventory costs, as well as management of new prescription and ordering requirements and additional demands for information sharing with CAP vendors. It would be advisable for CMS to evaluate the impact of participation in a CAP program on physician practices before they actually participate. It also would be advisable to remember that if drug related billings are removed from practice business, the revenue generation thresholds for

practices will drop several fold – thus making them qualify even more as small businesses subject to adverse impact of untested programs.

The CMS proposal suggests that "because the drug remains the property of the vendor until the time of administration, the physician can also reduce the cost associated with storage and individual drug supplier negotiations." This is an unrealistic perspective. The burden to the physician and the related costs actually increase under the CAP program due to the need for separate inventory management and running of concurrent inventories – both for staff and facility resources.

Sincerely,

Dawn Holcombe
Executive Director
Oncology Network of CT, LLC
425 Sullivan Avenue, Suite 1
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860-282-7282
dawnho@aol.com

Submitter :

Date: 04/26/2005

Organization : **Abbott Laboratories**

Category : **Drug Industry**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1325-P-429-Attach-1.DOC

[redacted]

Re: CMS Proposed Rule on Competitive Acquisition of Outpatient Drugs and Biological under Part B, 70 Fed. Reg. 10746 (March 4, 2005) [CMS-1325-P]

[redacted]

[redacted]s CMS drafts the CAP final rule, we recommend that the agency ensure that beneficiary access to clinically-appropriate drugs is preserved.

[redacted]We believe that CMS should carefully phase-in this new program on a state-wide or other limited geographic basis with a limited number of CAP vendors participating. This will enable CMS to more manageably address the numerous operational issues that undoubtedly will arise upon implementation.

[redacted]ecommend that the CAP final rule be issued as an interim final rule with a comment period to provide additional opportunity for stakeholder input.

Submitter : Mr. John Akscin **Date:** 04/26/2005

Organization : Oncology Therapeutics Network

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

OTN appreciates this opportunity to submit comments on the CMS Proposed Rule, "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B; Docket: CMS-1325-P
See attached.

Confirmation email: john.akscin@otnnet.com
Contact: 314-591-7799

CMS-1325-P-430-Attach-1.PDF

Privileged and Confidential

395 Oyster Point Boulevard, Suite 500
South San Francisco, CA 94080

April 26, 2005

Dr. Mark McClellan
Administrator
Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1325-P
P.O. Box 8010
Baltimore, MD 21244-1850

Dear Dr. McClellan:

Oncology Therapeutics Network (OTN),is a specialty distributor that manages the delivery of complex, breakthrough drugs and biologics to office based physicians, primarily in the specialties of hematology, oncology, rheumatology and urology. OTN submits these comments in response to the proposed rule for the competitive acquisition program (CAP) of outpatient drugs and biologicals under Part B ("proposed rule").[1] OTN recognizes the great strides that CMS has made in preparing to implement CAP in the proposed rule. We do wish, however, to further refine it in a manner that increases efficiencies for the Program, generates cost savings and maintains product safety. As such, all of the comments offered in these reply comments are provided in the spirit of assisting CMS in its efforts to create a workable delivery system under Medicare Part B.

OTN in participation with the other members of the Specialty & Biotech Distributors Association ("SBDA") has submitted comments to the proposed rule, which OTN strongly reiterates. In addition to the views expressed in the SBDA's comment letter (which for brevity have not been restated in this letter) OTN seeks to provide CMS with additional comments, as follows:

I. **Introduction to Oncology Therapeutics Network.**

II. **Identification of oncology specific challenges and risks under CAP as currently drafted.**

- *a. CAP vs. Buy/Bill Model*
- *b. Hidden costs of CAP*
- *c. Administrative burden*
- *d. Costs of "Day-of" treatment modifications*

[1] "Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B," 70 Fed. Reg. 10,745–10,773 (Mar. 4, 2005).

e. *Hazardous Waste Disposal*

III. **Highlight the differences between Specialty Distribution and Specialty Pharmacy.**

IV. **Provide insight to ensure integrity of products distributed throughout the pharmaceutical and biotech supply channel.**

V. **Discuss CAP Vendor qualifications and requirements.**

VI. **Recommend items for exclusion from list of enumerated discounts that determine the "net acquisition costs" of Part B drugs under the CAP program.**

a. *Prompt Pay*

b. *Time value of Money*

VII. **Recommend methods to provide Vendor compensation for assumption of risk.**

a. *Advanced payment*

b. *Co-pay collection*

VIII. **Recommend Phase-In of CAP.**

IX. **Summary of Recommendations.**

I. Introduction to the Oncology Therapeutics Network

Founded in 1990, OTN is the 2nd largest specialty distributor and leading specialty pharmacy distributor, primarily to office based oncologists. In fiscal 2004, OTN had gross revenues of over $3 billion. OTN's customer base includes more than 4000 community oncologists, representing over two thirds of all community oncology practitioners. In addition, OTN offers practices inventory management solutions and integrated office management solutions. OTN also distributes pharmaceutical and other supplies to more 1400 urology and 400 rheumatology practices. OTN has an excellent reputation for exemplary customer service and its commitment to enabling office based physicians to provide high quality patient care, with a long track record of expertise in pharmaceutical logistics and over 99.8% order delivery accuracy on a daily basis.

II. Identification of oncology specific challenges and risks under CAP as currently drafted

a. *CAP vs. Buy/Bill Model*

OTN believes that oncologists will face reimbursement shortfalls under both the Buy/Bill model and the CAP model due to the inadequacy of planned reimbursement for drug administration services. Under CAP these shortfalls will be even greater due the high administrative burden on the practices required to comply with CAP, including higher claims administration costs, inventory control and tracking, pharmacy management services, product integrity risks, additional hazardous waste disposal, additional liability risks (risks associated with product integrity, risks associated with interruptions and delays in patient treatment upon unanticipated drug

treatment changes). Many practices will incur a significant net loss and will be faced with the decision as to whether to discontinue offering services to Medicare beneficiaries, or worse yet, of closure. OTN does not believe that CMS intends to limit patient access to community cancer care, where over 80% of the most cost effective and highest quality treatment of cancer patients exists. Many Medicare cancer patients will be forced to hospitals to obtain their chemotherapy. This result seems to be the opposite of CMS's desired intent: to reduce costs and improve quality of and access to cancer care.

OTN's management feels that the ASP +6% methodology is an effective and sufficient way in which to achieve CMS's intent. In fact, we note that with the ASP +6% reimbursement methodology, CMS has already accomplished the following goals:

- Reduced the overall cost of care by decreasing the incidence of pharmaceutical price increases.
- Brought drug costs to the Medicare program more in line with prices paid for drugs in the marketplace.
- Preserved access to the high quality of patient care delivered by community oncology.

The benefits of ASP +6% continue to become apparent to CMS and its constituents. However, OTN is concerned that CAP will have significant unintended consequences that are counter to CMS' overall aims, and may in fact diminish some of the progress already made under ASP +6%. Unlike ASP +6%, CAP will not bring about significant efficiencies or additional cost savings for community oncology, but will substantially increase the administrative burden for these complicated disease states and adversely impact patient care.

b. Hidden Costs of CAP

OTN believes that CAP as currently drafted has the unintended effect of creating additional risks and costs in the delivery of oncology care. Some of these risks and costs are identified below.

- Costs for changes in therapy and wasted drug.
- Patient convenience and costs (multiple visits, increased travel to obtain drug).
- Lack of readily-available inventory of drugs (that are not designated for specific patients) for urgent needs potentially resulting in more referrals to hospital emergency rooms.
- Product integrity, Chain of control issues.
- Inventory inefficiencies (larger inventories required; no sharing of multi-

dose vials; no batch preparations; operations and workflow tailored to patient payor status rather than clinical efficiency; need to maintain multiple inventory systems).

- Larger volumes of hazardous waste (full vial wastage/higher disposal costs).
- Additional third party communication requirements and significant administrative burden.

c. Administrative Burden

The administrative burden of CAP on CMS, a CAP vendor and on a practice, must also be considered. The average practice will require additional staff for ordering from the CAP vendor, opening boxes from the vendor and checking the contents against the prescription, shelving and inventorying the contents, and making sure it is not used for anyone else. Additionally, if the patient does not arrive at the physician practice as scheduled, or cannot be treated for whatever reason, practice staff must take time away from treating patients to notify the CAP vendor and ship the product back. This will require that the practice has a tremendous amount of additional help. In fact, a clinic will need to develop a parallel claims processing capability for the CAP, which when coupled with the CAP vendor claims, is likely to substantially increase CMS' administrative costs of running the system and result in significant inefficiency.

OTN recommends that CMS evaluate the adequacy of the planned fee schedule under both the Buy/Bill Model and the CAP model, and institute additional administrative fees, such as a facility or pharmacy fees, to compensate physicians for these additional burdens.

d. Costs of "Day-of" treatment modifications

An open question, for example, is how the planned CAP system will deal with drugs that aren't administered as expected, a common occurrence unique to the oncology environment, as on average 30 % of patient treatment plans change when the patient presents for treatment due to factors such as low blood counts or clinical status change. This may raise both cost and patient convenience issues, as more office visits (and associated co-pays) may become necessary to complete a treatment regimen.

Returns and inventory control may also become larger concerns, as patient-specific drug supplies will need to be carefully segregated and controlled. It is unclear how the Medicare contracted CAP Vendors serving multi-state regions will deal with state law discrepancies related to returns. Some states in the region may allow returns and other may not. Either way, the issue of returning drugs to the CAP Vendor requires additional study and evaluation.

e. Hazardous Waste Costs

CAP as planned will likely increase hazardous waste disposal costs significantly as a result of higher quantities of unused drug from unanticipated treatment changes. Consequently, total waste quantities may significantly add to existing waste levels thus incurring additional disposal costs.

It is unclear which entity (the practice or the CAP vendor) will bear the burden of the hazardous waste disposal costs, including compliance with applicable federal, state and local laws regulating such disposal. Under the Proposed Rule there appears to be no financial consideration of this expense for either providers or CAP vendors. OTN recommends that the CAP vendor does not bear the responsibility for this, but that the physicians discard these drugs along with their other hazardous waste, since the product will already be at their practice. Regardless of which entity has responsibility for discarding hazardous waste, OTN believes that there should be appropriate consideration of this financial and operational burden in assessing reimbursement. OTN recommends a HCPCS code for "pharmacy services, including waste disposal."

III. Highlight differences Between Specialty Distribution and Specialty Pharmacy

Traditionally specialty distributors and specialty pharmacies have represented distinct elements of the supply chain. The CAP program appears to blend these roles as it contemplates contractors who will potentially inventory, distribute, and dispense drugs and biologicals based on patient specific orders. In the section on "Bidding Entity Qualifications," CMS notes that a CAP vendor "would be required to maintain an appropriate license in each State in which the drug vendor seeks to operate under the CAP." Because the CAP vendors will be accepting prescriptions for and dispensing Part B medicines, Medicare appears to be requiring each CAP vendor have state licensure as pharmacies in each state in which it operates as part of the CAP program. However, the CAP rule also indicates that vendors must also be licensed as distributors or wholesalers. Specialty distributors and pharmacies fall under entirely different aspects of state pharmacy laws, regulations and contractual arrangements.

OTN recommends that CMS clearly state whether it intends for vendors to operate under a specialty distribution model, a specialty pharmacy model, or an expanded specialty distribution/ "new hybrid" model. If CMS seeks to establish a new hybrid model, it will need to take these two disparate models and related compliance standards into account and consider establishing one straightforward set of rules for vendors to meet. Additionally, OTN recommends that CMS consider the added financial burdens for any vendor associated with a new hybrid model. Otherwise, the complexity in complying with multiple state licensing standards for both distributors and pharmacies will significantly discourage potential participation by vendors.

The chart below highlights some of the key differences between a specialty distributor and a specialty pharmacy that OTN recommends for consideration:

Specialty Distribution	Specialty Pharmacy
• Licenses to distribute drug • Requires home state	• Pharmacy Licenses allow dispensation and distribution of drug to patient

wholesaler licensure to ship drug in-state, and out of state licensure in only certain jurisdictions to ship drugs from out of state • No specific staffing requirements • Distributor does not own any prescription. Distributor owns inventory and sells inventory. Each sale of inventory is an "Order number" • Returns may be accepted under specific circumstances as dictated by the manufacturer • No prescription claims processing technology/ adjudication systems • HIPAA: Distributor is a "business associate" of a "covered entity", but not actually a "covered entity"	• In order to dispense product across state lines, must register with such state's pharmacy board as a "non-resident" pharmacy • Requires a licensed pharmacist on staff at all times of dispensing • Pharmacy OWNS the prescription, which is assigned a "prescription number". • Once medication is prescribed to a patient, if it is unused, it must be disposed of, UNLESS it is still in its original packaging. In that case it must be sent back to the original pharmacy. ONLY the dispensing pharmacy can re-dispense the drug to another patient. Each patient specific prescription must be checked against the product leaving the pharmacy. State laws prevent issuing a prescription number for drug already dispensed, without checking it against that prescription BY THE DISPENSING PHARMACY; • Claims processing, script adjudication capability (through PBM) required. • HIPAA: Pharmacy is a "covered entity," collecting patient health information. The above requirements are only for a pharmacy sending drugs "as is", with no mixing, preparation, etc required. Generally single dose vials. If the pharmacy does any admixing, preparation, etc. additional standards apply

A. Returns

One clear example of the differences between distributors and pharmacies exists in the area of the returns of drug and biological products. Many states do not permit pharmacies to accept returns from patients except under specific circumstances such as when the product is returned in a properly labeled and sealed manufacturer's package or if customized units are individually sealed and part of a closed-drug delivery system.[2] The Food and Drug Administration (FDA) also recommends that pharmacists not accept return of drug products once they have left his or her possession.[3] In contrast, specialty distributors may generally accept

[2] Fla. Admin. Code Ann. r. 64B16-28.118 (2005) (prohibiting returns by patients except for unused portions of a unit dose package dispensed to in-patients in a closed delivery system and if the drug is individually sealed and properly labeled); Md. Regs. Code tit. 10, § 10.34.10.07 (prohibiting returns to a pharmacy's stock of previously sold product unless the product is properly labeled and sealed or, in the case of a unit dose, the pharmacist determines the product to have been handled in a manner that preserves the strength, quality, purity, and identity of the drug).

[3] FDA Compliance Policy Guide § 460.300 (CPG 7132.09).

product returns under specific circumstances dictated by drug manufacturers. In some circumstances, distributors may be required to accept return of expired product.[4]

The proposed rule suggests that the issue of returns should be addressed between the physician and the distributor/pharmacy. However, while seemingly permissible under specialty distribution arrangements, this may not be feasible under various state pharmacy laws. Moreover, some organizations have suggested that vendors should bear the financial responsibility for all returns. OTN suggests mandated manufacturer acceptance so that the manufacturer bears some of this risk as well. Such a policy is inconsistent with today's practices and would render the CAP model untenable from a cost-management perspective.

There are other issues that CMS may wish to modify on its returns policy. Many of the products involved in CAP will require special storage and handling due to their sensitivity to temperature. Specialty distributors will, therefore, as a general matter, resist accepting some of the specialty products back into the supply channel, as product integrity cannot be verified. In addition, when you take into account that a significant amount of product may be "broken down" from original packaging by the CAP vendor in order to dispense a prescribed unit of dose, it is clear that product integrity would be jeopardized if specialty distributors were asked to accept these "broken down" returns –those that are not in the manufacturers' original, unopened packaging. At a minimum, CMS needs to be clear that broken down returns cannot be recycled back into the supply chain. To do otherwise, would actually violate the clear terms of the statute since the distributor would no longer be able to guarantee that it obtained product directly from the manufacturer.

B. Licensure Issues, Claims Processing and HIPAA

As CMS refines the CAP model in the final rule, it should also note the differences in licensure requirements between distributors and pharmacies. For example, pharmacies are often required to have licensed pharmacists on staff during hours of operation.[5] In general, although distributors may be required to report extensive information about distributor ownership and management, they face far fewer specific staffing requirements.[6] Additionally, a licensed pharmacy may generally interpret, evaluate, and dispense drug and biological products. Specialty distributors, however, manage inventory and ship product based on a drug order – not a prescription. Although specialty distributors may be registered or licensed by the state, they are not generally licensed to dispense drug product. If CMS is looking to establish a distribution model for CAP, it will need to consider how distributors will meet the additional standards required for specialty pharmacies. One federal licensing standard here should be appropriate.

Claims processing and adjudication represent other important distinctions between specialty distributors and pharmacies. Pharmacies must have the technical ability to process third-party payer claims, collect co-payments and adjudicate claims on a patient by

[4] *See, e.g.*, Ga. Code Ann. § 26-4-115(c) (instructing the Board of Pharmacy to promulgate rules for wholesale distributors that includes a requirement that distributors make adequate provisions for the return of outdated product); Ga. Comp. R. & Regs. r. 480-7-.07 (2004) (requiring wholesale distributors to make adequate provisions for the return of outdated prescription drug product for up to six months after the labeled expiration date).

[5] *E.g.*, Ga. Code Ann. § 26-4-110.

[6] *See, e.g.*, Fla. Stat. § 499.012 (enumerating requirements for applicants of wholesaler prescription drug permits).

patient basis. In contrast, distributors are not generally equipped to process such patient level claims and do not maintain systems or personnel who are trained to address these issues.

Treatment under HIPAA provisions is another distinguishing characteristic between specialty distributors and pharmacies. In the preamble to the proposed rule, CMS has indicated that vendors would be treated as "covered entities" under HIPAA provisions.[7] This classification varies from that of specialty distributors, who are considered "business associates" under the HIPAA laws and regulations. Classification as a "covered entity" imposes significant administrative burdens that "business associates" do not necessarily face. If CMS is interested in "converting specialty distributors" into CAP vendors, it must take into account the added administrative and financial burdens associated with complying with a different set of HIPAA rules.

These differences are important for CMS to understand as it develops policies for CAP contractors who will interact with manufacturers, wholesalers, specialty distributors and physician offices. If CMS seeks to establish a new hybrid model, it will need to take these two disparate sets of compliance standards into account and consider establishing one straightforward set of rules for vendors to meet.

IV. Integrity of products distributed throughout the pharmaceutical and biotech supply Channel

In light of the structural changes within Part B reflected in this proposal, it will be particularly important for CMS to establish product integrity standards that reflect the "best practices" of the distribution industry in the CAP program, but that also do not impose significant new requirements which offer no improvement in product integrity for Medicare beneficiaries.

OTN commends CMS for the requirement that CAP vendors shall acquire the drugs and biological products that they distribute from the manufacturer or from a distributor who has acquired the drug directly from the manufacturer.[8] This one requirement significantly protects product integrity under CAP by limiting purchases of potentially adulterated drugs from secondary markets. The proposed rule would also require CAP vendors to comport with applicable sections of the Federal Food, Drug, and Cosmetic Act, as well as to take appropriate measures "to assure that processing, handling, storage, and shipment of drugs and biologicals are adequate to maintain product integrity."[9] OTN supports these requirements and seeks to work with CMS to ensure compliance with federal law and manufacturer's product specifications.

Compliance with these fundamental requirements alone will significantly protect the integrity of CAP drug and biological products. New requirements beyond these protections, will create an additional burden on CAP contractors, and may harm the efficiency and effectiveness of the CAP program while offering no improvement in product integrity for Medicare beneficiaries. Due to the adequacy of existing requirements, OTN does not consider new requirements necessary or advisable.

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[7] 70 Fed. Reg. 10,745, 10,760 (Mar. 4, 2005).
[8] 70 Fed. Reg. at 10,759.
[9] 70 Fed. Reg. at 10,759.

V. CAP Vendor qualifications and requirements

OTN commends CMS in its decision to require CAP bidders to have been in the business of furnishing Part B injectable drugs for at least three years to qualify as a vendor in the CAP program.[10] This requirement ensures that CAP vendors have the requisite experience and stability to deliver timely service to physicians and Medicare beneficiaries. This experience also helps to ensure that CAP vendors are capable of furnishing product that meets all of the product integrity standards established in the proposed rule. OTN requests that CMS clarify that the term "furnishing" includes specialty distributor sales of products to providers under the buy and bill model, and also specialty pharmacy prescription model.

OTN also recommends that CMS consider the financial stability of the CAP contractor. Given the current risks of the program, it is entirely possible that a chosen contractor may become insolvent during the three year period of the contract. Establishing a threshold for potential bidders will help minimize the potential for bidders with a higher risk of insolvency being chosen for the program.

VI. Recommended items for exclusion from enumerated discounts determining "net acquisition costs" of Part B drugs under the CAP program

a. Prompt Pay

As part of the proposed rule, CMS will require CAP vendors to submit their "reasonable, net acquisition costs" for obtaining Part B medicines so that CMS may adjust the contract prices in year 2 and 3 of the contract.[11] These net acquisition costs represent "[a]ctual acquisition costs [that] are net of all discounts and rebates provided by the vendor's own suppliers."[12] Discounts enumerated by CMS include "volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, rebates, refunds, and other price concessions." With respect to the calculation of vendors' bid prices, OTN notes that CMS should not include bona fide prompt pay discounts into the contractor's bid submission. Such credit practices, so long as they undertaken at fair market value and are not passed on to the provider, do not constitute price concessions and should not be treated in the same manner as a traditional price discount. In fact, OTN notes that it would be inconsistent for CMS to include the entirety of prompt pay discounts into bids, if the Agency were to remain consistent to its recent interpretations of the Part B Average Sales Price provisions. Given that the fair market value of bona fide services can be excluded from ASP – and prompt pay discounts currently reflect a large portion of the revenues used to reimburse entities for distribution *services* – then there is no logic for including most of the prompt pay terms in either the CAP vendor contract price or ASP. So long as the contract terms represent fair market value, arms length transactions and do not result in a reduction of the price actually realized by the manufacturer, CMS should not include them in the bid price.

b. Time value of Money

[10] 70 Fed. Reg. at 10,760.
[11] 70 Fed. Reg. at 10,764.
[12] 70 Fed. Reg. at 10, 765.

OTN believes that the principle of the time value of money should be appropriately considered when determining when CAP contractors may receive payment for product shipped under the CAP program. The importance of the time value of money is evident in the CAP program. Under the proposed CAP rule, physicians are generally required to bill their claims within 14 calendar days of the date the drug was administered to the beneficiary.[13] CAP vendors would not receive payment for the Part B product, nor be permitted to bill the beneficiary or the beneficiary's third-party insurance for the copayment, until both the vendor claim and physician claim had been reconciled.[14] Even were the system to operate flawlessly, vendors would experience a greater than 28 day delay in payment between shipment of the drug, physician submission of the drug claim, and carrier reconciliation of the physician and CAP contractor claims. During this delay the CAP vendor would receive no payment for the lost interest that could have accumulated risk-free. Although the time period under this scenario may be appear to be 28 days under optimal conditions, in reality delays of greater than 30 days will most likely be the norm. Any delays represent a significant amount of lost revenue for the CAP vendors.

VII. Recommended methods to provide Vendor compensation for assumption of risk

The present financial remuneration as outlined in the proposed rule places undue financial hardship on the CAP vendors. Financial risks such as claims rejection for drugs denied for lack of med necessity, payments based upon the median of all bids from CAP vendors and not on a specific CAP vendors bid, costs of wasted drug, and uncollectible co-payments from patients will most likely eliminate any potential for a CAP vendor to break even under CAP. We ask CMS to consider the following to help mitigate these risks:

a. Precertification:

OTN suggests CMS institute a pre-certification process to permit physicians and CAP vendors the opportunity to verify medical necessity before a drug order is filled. Under the proposed rule, physicians bare no risk for denial of drug claims and CAP vendors ability to win appeal of such claims is highly dependent on the cooperation of the physicians whose financial incentive is limited solely to payment for the drug administration services.

b. Advanced payment

OTN notes that few mechanisms exist within the proposed rule to encourage physicians to submit their claims on a timely basis.[15] Hopefully, the potential threat of suspension of a physician's CAP participation agreement should motivate physicians to submit their CAP claims in a timely manner.[16] However, intermediate steps may also be required. Absent providing the contractors with some new mechanism or enforcement tool, it is quite likely that their ability to eventually realize all of the claims owed to them will be reduced. Other than the above listed threat (not necessarily considered meaningful for physicians), the physician has no real risk at stake by not filing the claim in a timely manner. However, the CAP vendor has a significant risk at stake. OTN believes that the vendor must be compensated for this risk, and

[13] 70 Fed. Reg. at 10,755.
[14] 70 Fed. Reg. at 10,756.
[15] 70 Fed. Reg. at 10,758.
[16] 70 Fed. Reg. at 10,758.

encourages CMS to adopt partial payment of the CAP vendor's claim upon shipment of the product and with the remaining payment due upon receipt of the drug administration claim by the carrier. This would lessen the financial harm experienced by the vendor from physician claim submission delays and at least attempts to account for the time value of the funds committed by the CAP vendors in the form of shipped product to physicians.

This provision appears especially equitable because the risk of non-payment when the physician fails to file a claim rests on the CAP vendor, who must expend time and resources to informally encourage the physician to file the appropriate claim or engage in the dispute resolution provisions proposed by CMS. We note that some type of enforcement is important in the event that informal processes fail to encourage timely filing of physician claims.

c. Co-pay collection

OTN notes that CMS should consider permitting a contracted relationship between the CAP vendor and the physician, incenting the physician to collect the co-pay at the time of care. Given the relationship between the physician and the patient, it is much more likely that the physician will be able to capture a co-pay than a vendor, with no perceived relationship to the patient. The physician could be incented to capture the co-pay on behalf of the vendor by obtaining a "collection fee" which would cover any associated administrative burden in doing so. Additionally, OTN believes that this method is not only preferable for the CAP vendor, but also for the patient and the physician, since it eliminates the possibility of overly aggressive collection efforts by the CAP vendor which could ultimately discourage patients from seeking treatment. Lastly, this recommendation also minimizes the potential to exacerbate a vendor's bad debt collection problems.

VIII. Phase-in of CAP recommended

Because of the complexities involved in the implementation of CAP, OTN strongly believes that this new system must be phased in slowly. Significant questions have arisen with respect to the leverage that contractors would actually possess under the proposed rule to manage prescription drug costs and the attendant level of risk that would be borne by the contractor during the three year contract period. Accordingly, OTN believes it most effective for the long term success of the program if CMS phased in CAP for one physician specialty, starting with a specialty with fewer complexities and risks to patients quality of and access to care than oncology, over a three-year period and limited the program to one geographic region for the first two years. OTN management believes that commencing the phase-in with Rheumatology is advisable, given that Rheumatoid Arthritis has fewer complexities and is much better suited to CAP. Working with appropriate stakeholders, CMS could utilize the multi-year phase in period to overcome the regulatory and statutory obstacles that may impede the establishment of a successful program.

OTN respectfully recommends than CMS should begin with a regional phase-in involving a limited set of drugs that are typically administered by a physician specialty with fewer complexities and risks to patient quality and access of care than oncology, thereby allowing time for refinement in the issues identified above. OTN appreciates your consideration of these positions and welcomes the opportunity to meaningfully contribute to the development of the the final rule.

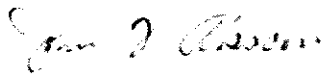
XI. Summary of Recommendations

1. CMS needs to further clarify its intention and design of a CAP vendor as it relates to specialty distribution.
2. OTN asks CMS to reconsider the significant administrative burden to both CAP vendors and medicare providers associated with the CAP program
3. CMS needs to understand and address the significant financial risk borne by CAP vendors relating to the payment structure set forth in the Proposed Rule
4. OTN asks CMS to strongly consider phase in of the CAP program in both a single specialty, limited to certain drugs, and rolled out in one region.
5. OTN understands the statutory requirements placed upon CMS by MMA, however the potential waste, administrative burden to CAP vendors, providers and the CMS system, financial risks, and reductions in quality of care to cancer patients warrant continued evaluation and alternative solutions.

OTN thanks you for this opportunity to provide comments to the CAP program.

John Amos
President
Oncology Therapeutics Network

William Kushner
General Counsel
Oncology Therapeutics Network



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